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Mapping Our Future: The Impact of Gene Patents on Scientific Research and Health Care in the United States

Caitlin E. Lanning

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MAPPING OUR FUTURE: THE IMPACT OF GENE PATENTS ON SCIENTIFIC RESEARCH AND HEALTH CARE IN THE UNITED STATES

CAITLIN E. LANNING*

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I. INTRODUCTION

Kathy Hopkins was the eldest of seven children. She was a single mother, and the sole supporter of her son. In the spring of 2007, Kathy was diagnosed with stage four glioblastoma multiform (“GBM”). GBM is a compilation of small tumors within the glia or the precursors of the glia within the central nervous system.¹ This form of brain cancer is “the most aggressive of the gliomas.”² Most individuals with

* J.D. Cleveland State University, Cleveland-Marshall College of Law, 2013; B.S. John Carroll University, 2010. Thank you to my loving family and friends for their continuous support. A special thank you to Lisa Gasbarre Black, Esq., my mentor and dear friend. Lastly, I would like to dedicate this Note to the memory of my beloved Aunt Katherine Hopkins.

¹ Eric C. Holland, *Glioblastoma Multiforme: The Terminator*, 97(12) PNAS 6242, 6242 (2000), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC33993/pdf/pq006242.pdf>.

² *Id.* The medical community has “evaded increasingly clever and intricate attempts at therapy over the last half-century.” *Id.* The latest treatment implements “a hybrid virus that infects and kills clonal human glioma cell lines.” *Id.* This treatment has been tested in athymic mice successfully “without affecting nonneoplastic cells within the brain.” *Id.*

GBM die in less than a year from the date of diagnosis.³ Even with treatment, the life expectancy of individuals diagnosed with GBM only increases from two months to a year.⁴ Kathy's tumor was inoperable. Her only options for treatment included chemotherapy and radiation. Determined that the medical community would discover a cure, Kathy chose to try every medical procedure available in hopes that she could defeat GBM. On April 1, 2009, two years after her diagnosis, at the age of 63, Kathy passed away surrounded by her loving family.⁵

Greg Knittel was the Classics' Chairman, Dean of Teachers, and founding soccer coach at St. Ignatius High School in Cleveland, Ohio.⁶ Greg, fondly known by his students and the Ignatius community as "Doc," was forced to retire from St. Ignatius when he lost the ability to control his car on his drive into work.⁷ Greg was suffering from amyotrophic lateral sclerosis ("ALS").⁸ The major cause(s) of ALS, also commonly referred to as Lou Gehrig's⁹ disease, are unknown.¹⁰ Ten percent of all ALS cases are genetically based.¹¹ ALS causes neurons¹² to slowly waste away

³ *Id.*

⁴ *Id.*

⁵ The story of Kathy Hopkins was taken from the author's personal experiences.

⁶ Grant Segall, *Greg Knittel was Dean, Chairman and Soccer Coach at St. Ignatius: News Obituary*, CLEVELAND PLAIN DEALER, Feb. 8, 2013, http://www.cleveland.com/obituaries/index.ssf/2013/02/greg_knittel_was_dean_chairman.html (last visited Feb. 17, 2013). Greg had an extensive educational and extracurricular background. *Id.*

He attended College of the Holy Cross in Worcester, Mass. He earned a bachelor's degree from John Carroll University and went on to a master's at the University of California at Santa Barbara. He taught at high school in Santa Barbara for two years. Knittel rejoined Ignatius in 1974 to teach classics and started the soccer team two years later. He stopped coaching in 1985 to earn a doctorate from Kent State University. He coached again from 1990 through 1994. His teams had 161 wins, 61 losses and 31 ties. He was inducted into the school's Athletic Hall of Fame twice: as coach and as part of the 1964 football team, which was inducted as a group. He was twice named area soccer coach of the year and once Ignatius' teacher of the year.

Id.

⁷ *Id.*

⁸ Gregory Joseph "Doc" Knittel Ph.D, *Obituaries & Guestbook*, CLEVELAND PLAIN DEALER, Feb. 8, 2013, <http://obits.cleveland.com/obituaries/cleveland/obituary.aspx?n=gregory-joseph-knittel-doc&pid=162929249&fhid=15566#fbLoggedOut>; *Amyotrophic Lateral Sclerosis: Lou Gehrig's Disease; ALS; Upper and Lower Motor Neuron Disease; Motor neuron disease*, PUBMED HEALTH, <http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0001708/> (last updated Aug. 26, 2012).

⁹ Henry Louis Gehrig played for the New York Yankees during the 1920s and 1930s. *Lou Gehrig*, BIOGRAPHY.COM, <http://www.biography.com/people/lou-gehrig-9308266?page=1> (last visited Feb. 17, 2013). A member of the Baseball Hall of Fame, Gehrig as a Yankees first basemen set the mark for consecutive games played until he was forced to retire due to ALS. *Id.* "His diagnosis with the disease helped put the spotlight on the condition, and in the years since Gehrig's passing, it has come to be known popularly as 'Lou Gehrig's disease.'" *Id.*

¹⁰ *Amyotrophic lateral sclerosis: Lou Gehrig's Disease*, *supra* note 8.

¹¹ *Amyotrophic lateral sclerosis: Lou Gehrig's Disease*, *supra* note 8.

and eventually die, resulting in “muscle weakening, twitching, and eventually the inability to move the arms, legs, and body.”¹³ This is caused by the inability of neurons to “send messages to [the] muscles” of the body after neurons have died.¹⁴ Individuals with ALS typically die within three to five years after being diagnosed.¹⁵ Only about twenty five percent of individuals diagnosed with ALS live beyond five years.¹⁶ On February 5, 2013 Greg “Doc” Knittel passed away surrounded by his loving family.¹⁷

Kathy and Greg are only two individuals, out of millions, who have suffered or who are currently suffering from incurable diseases. Scientists are in a race to discover new diagnostic technologies and treatments to bring an end to human anguish through the rapidly growing field of genetics. While cures are within the grasp of humanity’s fingertips, current gene patent regulations act as roadblocks to

¹² A neuron is “[a]ny of the impulse-conducting cells that constitute the brain, spinal column, and nerves, consisting of a nucleated cell body with one or more dendrites and a single axon. Also called *nerve cell*.” *Neuron*, FREE ONLINE DICTIONARY, THESAURUS, AND ENCYCLOPEDIA, <http://www.thefreedictionary.com/neuron> (last visited Nov. 24, 2011).

¹³ *Amyotrophic lateral sclerosis: Lou Gehrig’s Disease*, *supra* note 8.

¹⁴ *Amyotrophic lateral sclerosis: Lou Gehrig’s Disease*, *supra* note 8.

¹⁵ *Amyotrophic lateral sclerosis: Lou Gehrig’s Disease*, *supra* note 8.

¹⁶ *Amyotrophic lateral sclerosis: Lou Gehrig’s Disease*, *supra* note 8.

¹⁷ The story of Greg “Doc” Knittel was taken from the author’s personal experiences. Another ALS story is that of Jim Ziegler:

Jim Ziegler was a humble, generous man who made his mark on the world for the 62 years he was a part of it. In the summer of 2010, Jim began experiencing muscle pains in his legs, particularly when engaging in physical activity. On one occasion, his friends had to carry him off the golf course because the pain became so severe that it was unbearable for Jim to walk. Jim visited his doctor that fall and spoke of the symptoms he had been experiencing, and it was on that day that his fate was confirmed. At the age of 61, my uncle was diagnosed with ALS. Jim’s diagnosis came in September of 2010, and he passed away on April 29, 2011. The case my uncle suffered from was especially aggressive, and stole his ability to walk or even move his arms and legs within a few months of his diagnosis. For as much pain and suffering that he went through with this terrible disease, Jim was incredibly patient and willing to accept his fate. For as quickly as the disease progressed through Jim’s body, it took him away from us just as swiftly. In honor of Jim Ziegler and the legacy he left behind, our family has participated in the Walk to Defeat ALS in hopes of contributing to fund future research that will find a will cure to this debilitating and fatal disease.

Interview with Riannon Ziegler, Third Year Law Student, Cleveland-Marshall College of Law, Cleveland State University, Cleveland, Ohio (Jan. 13, 2013). The ALS Association is one of “the largest privately-funded research enterprise[s] engaged to uncover the mystery of a disease that affects as many as 30,000 annually.” *About Us*, Walk to Defeat ALS, THE ALS ASSOCIATION, http://web.alsa.org/site/PageServer?pagename=WLK_BP_aboutus (last visited Feb. 18, 2013). Over the past 10 years, the ALS Association has contributed about forty-eight million dollars to research. *Id.* “The ALS Association symbolizes the hopes of people everywhere that [ALS] will one day be a disease of the past relegated to historical status, studied in medical textbooks, conquered by the dedication of thousands who have worked ceaselessly to understand and eradicate this perplexing killer.” *Id.*

uncovering such discoveries. Gene patents have long been a topic of debate, first with the discovery of DNA, and later with the Human Genome Project and the HapMap Project, which resulted in the discovery of the complete sequence of the human genome and further discoveries of gene sequences.¹⁸

In September, 2011, the Senate passed H.R. 1249, the Leahy-Smith America Invents Act (“AIA”), which President Barack Obama signed into law on September 16th.¹⁹ The AIA is the largest transformation to U.S. patent law since 1952.²⁰ While the new legislation implements numerous, positive changes to the U.S. patent system, it fails to address any of the concerns raised by gene patent critics over the past few decades.²¹ Gene patents should be categorized as patentable subject matter within the AIA, but under a separate patent category with specifically engineered regulations designed to promote scientific research and collaboration that will in turn foster quicker results in diagnostic technologies and treatments.

Part I of this Note provides an educational background on genetics. Part II provides a background on the U.S. patent system, taking a historical look at patent legislation and case law, as well as the societal views surrounding gene patents. In general, this section analyzes the debate on whether genetic materials are patentable subject matter within the scope of 35 U.S.C. § 101. Part III lays a foundation of the AIA, and examines whether the new patent legislation properly regulates gene patents to stimulate and regulate scientific research and development. Part IV analyzes the need for new regulations specifically designed for gene patents within the AIA, and proposes detailed guidelines to achieve stricter, more appropriate regulations for gene patents.

¹⁸ *International Consortium Launches Genetic Variation Mapping Project: HapMap will Help Identify Genetic Contributions to Common Diseases*, NATIONAL HUMAN GENOME RESEARCH INSTITUTE, <http://www.genome.gov/10005336> (last visited Oct. 24, 2011).

The genome is an organism’s complete set of DNA. Genomes vary widely in size: the smallest known genome for a free-living organism (a bacterium) contains about 600,000 DNA base pairs, while human and mouse genomes have some 3 billion. Except for mature red blood cells, all human cells contain a complete genome.

From the Genome to the Proteome, HUMAN GENOME PROJECT SCIENCE, http://www.ornl.gov/sci/techresources/Human_Genome/project/info.shtml (last visited Oct. 24, 2011).

¹⁹ *President Obama Signs America Invents Act, Overhauling the Patent System to Stimulate Economic Growth, and Announces New Steps to Help Entrepreneurs Create Jobs*, THE WHITE HOUSE (Sept. 16, 2011), <http://www.whitehouse.gov/the-press-office/2011/09/16/president-obama-signs-america-invents-act-overhauling-patent-system-stim> (last visited Oct. 10, 2011).

²⁰ I-1 CHISUM ON PATENTS §1.01 (LexisNexis 2011).

²¹ *Compare* Eric D. Zard, *Patentability of Human Genetic Information: Exploring Ethical Dilemmas Within the Patent Office and Biotechnology’s Clash with the Public Good*, 6 U. ST. THOMAS L.J. 486, 493 (2009) (establishing the concerns regarding gene patents), *with* The Leahy-Smith America Invents Act, H.R. 1249, 120th Cong. (2011) (enacted), *reprinted in* www.uspto.gov/aia_implementation/bills-112hr1249enr.pdf (failing to address the concerns established by critics of gene patents).

II. GENETICS 101: BASIC EDUCATIONAL FOUNDATION

A. *Dissecting the Double Helix of Deoxyribonucleic Acid*

An organism's complete set of deoxyribonucleic acid (DNA)²² is known as its genome.²³ DNA is arranged in the nucleus of each cell within the human body.²⁴ Each nucleus contains two sets of chromosomes, one set given by each parent, for a total of forty-six chromosomes.²⁵ Each chromosome contains a single strand of DNA.²⁶ The DNA double helix is a linear arrangement of repeating nucleotides.²⁷ Nucleotides are composed of one sugar, one phosphate, and a nitrogenous base.²⁸ A nucleotide can contain one of four nitrogenous bases: adenine (A), guanine (G), cytosine (C), or thymine (T).²⁹ These bases pair up with one another, A with T, and C with G, to form base pairs.³⁰ The order of these base pairs "determines the information available for building and maintaining an organism, similar to the way in which letters of the alphabet appear in a certain order to form words and sentences."³¹

A gene is "a specific sequence of nucleotides in DNA" found on a chromosome.³² The specific sequence of nucleotides "determine[s] how, when, and where the body makes each of the many thousands of different proteins required for

²² DNA is the hereditary material found in all multi-celled organisms. *An Overview of the Human Genome Project*, NATIONAL HUMAN GENOME RESEARCH INSTITUTE, <http://www.genome.gov/12011238> (last visited Oct. 25, 2011).

²³ *From the Genome to the Proteome*, *supra* note 18. Deoxyribonucleic acid ("DNA") was first identified by Friedrich Miescher, a Swiss chemist, in the late 1860s. Leslie A. Pray, *Discovery of DNA Structure and Function: Watson and Crick*, NATURE EDUCATION, <http://www.nature.com/scitable/topicpage/discovery-of-dna-structure-and-function-watson-397> (last visited Oct. 24, 2011). Friedrich Miescher identified what he termed a "nuclein" inside the nuclei of a human white blood cell. *Id.* "The term 'nuclein' was later changed to 'nucleic acid' and eventually to 'deoxyribonucleic acid,' or 'DNA.'" *Id.* In addition to Miescher's contributions, Phoebus Levene and Erwin Chargaff research uncovered the primary chemical components of DNA, as well as how each chemical component joins with one another. *Id.* In 1953, James Watson and Francis Crick discovered the three-dimensional double helix structure of DNA. *Id.*

²⁴ *Handbook: Help Me Understand Genetics*, GENETICS HOME REFERENCE 9, <http://ghr.nlm.nih.gov/handbook.pdf> (last visited Feb. 18, 2013).

²⁵ *Id.* at 15.

²⁶ *Chromosomes FAQs*, HUMAN GENOME PROJECT INFORMATION, http://www.ornl.gov/sci/techresources/Human_Genome/posters/chromosome/faqs.shtml (last visited Nov. 24, 2011).

²⁷ *Id.*

²⁸ *Id.*

²⁹ *Handbook: Help Me Understand Genetics*, *supra* note 24, at 9.

³⁰ *Handbook: Help Me Understand Genetics*, *supra* note 24, at 9.

³¹ *Handbook: Help Me Understand Genetics*, *supra* note 24, at 9.

³² *Gene*, MERRIAM-WEBSTER ONLINE DICTIONARY, <http://www.merriam-webster.com/dictionary/gene> (last visited Oct. 24, 2011).

life.”³³ “Genes make up less than [two] percent of human DNA.”³⁴ The remaining DNA has important functions; however, those functions are still unknown.³⁵ It is speculated that those functions could “include regulating genes and maintaining the chromosome structure.”³⁶ When a nitrogenous base changes within the nucleotide of a gene, disorders and diseases result.³⁷ For example, “cystic fibrosis”³⁸ (chromosome 7) and sickle cell anemia³⁹ (chromosome 11) are caused by base sequence changes in a single gene.⁴⁰ Common diseases, such as cancer and diabetes, have complex causes that could be the result of base sequence changes on several genes encompassing several chromosomes.⁴¹ In 1990, a project called the Human Genome Project was orchestrated to learn more about the makeup of human DNA and genetic material.⁴³

B. The Human Genome Project

The Human Genome Project (“HGP”) was a collaborative, international research project aimed at producing a complete map of the human genome.⁴⁴ The project was

³³ *Chromosome FAQs*, *supra* note 26.

³⁴ *Chromosome FAQs*, *supra* note 26.

³⁵ *Chromosome FAQs*, *supra* note 26.

³⁶ *Chromosome FAQs*, *supra* note 26.

³⁷ *Chromosome FAQs*, *supra* note 26.

³⁸ Cystic Fibrosis, commonly referred to as CF, “is caused by a defective gene which causes the body to produce abnormally thick and sticky fluid, called mucus,” that builds up in the lungs and pancreas. *Cystic Fibrosis*, PUBMED HEALTH, <http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0001167> (last visited Feb. 17, 2013). The collection of mucous in the respiratory system and pancreas “results in life-threatening lung infections and serious digestion problems.” *Id.* The average lifespan of individuals with CF is about thirty-seven. Individuals with CF typically die due to lung complications. *Id.*

³⁹ Sickle cell anemia is a genetic disease that results in an abnormal crescent or sickle shaped red blood cell. *Sickle Cell Anemia*, PUBMED HEALTH, <http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0001554/> (last visited Feb. 18, 2013). Normally, red blood cells are shaped like a disc. *Id.* Individuals with sickle cell anemia have an abnormal type of hemoglobin known as hemoglobin S. *Id.* Hemoglobin is a protein that carries oxygen that is located within a red blood cell. *Id.* “Sickle cell disease is much more common in people of African and Mediterranean descent.” *Id.*

⁴⁰ *Chromosome FAQs*, *supra* note 26.

⁴¹ *Chromosome FAQs*, *supra* note 26.

⁴² An organism’s complete set of DNA is known as its genome. *From the Genome to the Proteome*, *supra* note 18.

⁴³ *An Overview of the Human Genome Project*, *supra* note 22.

⁴⁴ *An Overview of the Human Genome Project*, *supra* note 22. The United States National Institute of Health (NIH) and the Department of Energy funded the HGP. *The Human Genome Project: A New Reality*, WELLCOME TRUST SANGER INSTITUTE, <http://www.sanger.ac.uk/about/history/hgp/> (last visited Feb. 18, 2013). Specifically the goals for HGP included the following: (1) to identify the 20,000-25,000 genes in the human genome; (2) to determine the sequences of the nitrogenous base pairs that make up the human DNA; (3) to store the gathered information in a database; (4) “to improve tools for data analysis;” (5) “to transfer

expected to take fifteen years, but was completed in 2003.⁴⁵ The HGP decoded the human genome in three ways.⁴⁶ First, it determined the sequence of all the nitrogenous bases that comprise DNA.⁴⁷ Second, it produced maps of gene locations and sections of chromosomes.⁴⁸ Third, it produced linkage maps to track inherited traits over generations.⁴⁹ The full genetic sequence of the human genome was completed in April 2003, which revealed about 20,500 human genes.⁵⁰ Knowledge regarding the make-up of DNA and the sequences that compose genes has and will continue to lead to revolutionary mechanisms in research, technology, diagnoses, treatments, and preventive measures in healthcare, and within medical fields.⁵¹

the related technologies to the private sector, and” (6) “to address the ethical, legal, and social issues that arise from the project.” *About Human Genome Project*, HUMAN GENOME PROJECT INFORMATION, http://www.ornl.gov/sci/techresources/Human_Genome/project/about.shtml (last visited Oct. 25, 2011). While the HGP was being launched, John Sulston in the UK began “mapping the genome of [a] nematode worm” *The Human Genome Project: A New Reality*, *supra* note 44. Sulston approached the Wellcome Trust to form a new partnership, at which time Wellcome suggested Sulston and his group get involved in the HGP. *Id.* By the end of 1993, Sulston and his group of scientists began assisting in the quest of the HGP. *Id.*

⁴⁵ *About Human Genome Project*, *supra* note 44.

⁴⁶ *An Overview of the Human Genome Project*, *supra* note 22. Researchers used the hierarchical shotgun method to accurately sequence the human genome. *The Human Genome Project: A New Reality*, *supra* note 44. “Researchers agreed that this was the best way to achieve the Human Genome Project’s target of 95% coverage of the human genome by 2005.” *The Human Genome Project: A New Reality*, *supra* note 44. There are two main strategies when it comes to sequencing a genome. The first method is the hierarchical shotgun method as implemented by the HGP. *The Human Genome Project: A New Reality*, *supra* note 44. The second method is the shotgun sequencing method:

The advantage to the hierarchical approach is sequencers are less likely to make mistakes when assembling the shotgun fragments into contigs as long as full chromosomes. The reason is that the chromosomal location for each BAC is known, and there are fewer random pieces to assemble. The disadvantage to this method is time and expense. The shotgun method is faster and less expensive, but it is more prone to errors due to incorrect assembly of finished sequence.

The Human Genome Project: A New Reality, *supra* note 44. The size and complexity of the genome is what determines which sequencing method is better to use. *The Human Genome Project: A New Reality*, *supra* note 44.

⁴⁷ *An Overview of the Human Genome Project*, *supra* note 22.

⁴⁸ *An Overview of the Human Genome Project*, *supra* note 22.

⁴⁹ *An Overview of the Human Genome Project*, *supra* note 22.

⁵⁰ *An Overview of the Human Genome Project*, *supra* note 22. The number of genes found by the HGP was significantly less than what had been estimated by researchers. *An Overview of the Human Genome Project*, *supra* note 22. Researchers believed that between 50,000 and 140,000 genes existed within the human genome. *An Overview of the Human Genome Project*, *supra* note 22.

⁵¹ *An Overview of the Human Genome Project*, *supra* note 22.

C. The HabMap Project

Concurrently with the HGP, the International HapMap⁵² Consortium launched the International HapMap Project (HapMap Project) in 2002.⁵³ The HapMap Project was “aimed at speeding [up] the discovery of genes related to common illnesses [and diseases].”⁵⁴ Uncovering the genetic variations that lead to common diseases such as Alzheimer’s, cancer, and diabetes is difficult because these disorders are caused by variations in multiple genes versus a single variation within one gene.⁵⁵ The variations in the nitrogenous bases within DNA are called single nucleotide polymorphisms (SNPs).⁵⁶ A set of SNPs found on the same chromosome is known as a haplotype.⁵⁷ The HapMap Project produced a public database of the SNPs and haplotypes that the project uncovered in order to share the results internationally with other scientists.⁵⁸ Scientists use SNPs and haplotypes to compare the genetic differences between healthy individuals and individuals with common diseases.⁵⁹ By

⁵² “HapMap stands for ‘Haplotype Map.’” *You and the \$1000 Genome Part II: The International HapMap Project*, THE GENETIC GENEALOGIST, <http://www.thegeneticgenealogist.com/2007/05/24/you-and-the-1000-genome-%E2%80%93-part-ii-the-international-hapmap-project/> (last visited Nov. 7, 2011).

⁵³ David Secko, *Phase I of HapMap Complete*, THE SCIENTIST: MAGAZINE OF HEALTH SCIENCES, <http://classic.the-scientist.com/news/20051026/01/> (last visited Oct. 24, 2011).

⁵⁴ *International Consortium Launches Genetic Variation Mapping Project: HapMap will Help Identify Genetic Contributions to Common Diseases*, *supra* note 18. The HapMap Program is a catalogue of SNPs “that maps the natural organization of the human genome in blocks called haplotypes.” David Secko, *supra* note 53.

During the study, researchers took 296 DNA samples from four populations in Nigeria, Tokyo, Beijing, and Utah, aiming to genotype one SNP for every 5kb of genome. They characterized over one million SNPs, verified the low haplotype diversity in the above populations, and created a fine-scale genetic map of 21, 617 recombination hotspots.

Id. The second phase of the HapMap Project “analyzed an additional 2.1 million[] SNPs.” *Id.*

⁵⁵ *International Consortium Launches Genetic Variation Mapping Project: HapMap will Help Identify Genetic Contributions to Common Diseases*, *supra* note 18.

⁵⁶ *International Consortium Launches Genetic Variation Mapping Project: HapMap will Help Identify Genetic Contributions to Common Diseases*, *supra* note 18.

⁵⁷ *Haplotype*, NATIONAL HUMAN GENOME RESEARCH INSTITUTE, <http://www.genome.gov/Glossary/index.cfm?id=99> (last visited Oct. 25, 2011). A haplotype is “a set of DNA variations, or polymorphisms, that tend to be inherited together.” *Id.* “A haplotype can refer to a combination of alleles or to a set of single nucleotide polymorphisms (SNPs) found on the same chromosome. Information about haplotypes is being collected by the International HapMap Project and is used to investigate the influence of genes on disease.” *Id.*

⁵⁸ Secko, *supra* note 53.

⁵⁹ *International Consortium Launches Genetic Variation Mapping Project: HapMap will Help Identify Genetic Contributions to Common Diseases*, *supra* note 18. This method of research is known as an association study. *International Consortium Launches Genetic Variation Mapping Project: HapMap will Help Identify Genetic Contributions to Common Diseases*, *supra* note 18. “If the association study finds a certain haplotype more often in the people with the disease, researchers would then zero in on that genomic region in their search for the specific genetic variant. The tag SNPs would serve as signposts indicating that a

looking at the differences in genetic variations between individuals with a disease and healthy individuals, researchers can uncover the specific genetic sequences responsible for particular illnesses and diseases, and in turn, work towards uncovering treatments and eventually cures.⁶⁰

D. *The Future of Genetic Research*

The HGP and the HapMap Project have greatly amplified genetic studies and research around the world, which has resulted in an increase of patent applications.⁶¹ Within the United States alone, 3,000 to 5,000 patents on human genes have been issued, as well as around 47,000 patents for inventions related to genetic material.⁶² While patenting is widely accepted around the world, “many countries limit the scope of gene patents as a way to minimize the negative impact on health care costs and on the free flow of information in research.”⁶³

The United States had the opportunity to limit the scope of gene patents when the government issued the AIA in September 2011; however, no measures to regulate gene patents were outlined in the new law.⁶⁴ Gene patents should not be categorized as utility patents under the AIA. Instead gene patents should be categorized in a separate patent category, specifically designed to promote scientific research and collaboration. This in turn will advance scientific breakthroughs in health and science, resulting in positive diagnoses and treatments, thus saving millions of lives.

III. THE HISTORY OF THE U.S. PATENT SYSTEM AND THE EFFECT OF THE LEAHY-SMITH AMERICA INVENTS ACT

A. *Legislative History of the United States Patent System*

Under Article I, Section 8 of the United States Constitution, Congress has the power “to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Investors the exclusive Right to their respective Writings and

genetic variant involved in the disease may lie nearby.” *International Consortium Launches Genetic Variation Mapping Project: HapMap will Help Identify Genetic Contributions to Common Diseases*, *supra* note 18. Research has proven “that any two people are 99.9 percent identical at the genetic level, the 0.1 percent difference is important because it helps explain why one person is more susceptible to a specific disease – say diabetes – than someone who is less susceptible.” *International Consortium Launches Genetic Variation Mapping Project: HapMap will Help Identify Genetic Contributions to Common Diseases*, *supra* note 18.

⁶⁰ *International Consortium Launches Genetic Variation Mapping Project: HapMap will Help Identify Genetic Contributions to Common Diseases*, *supra* note 18.

⁶¹ “A patent for an invention is the grant of a property right to the inventor, issued by the United States Patent and Trademark Office.” *General Information Concerning Patents*, UNITED STATES PATENT AND TRADEMARK OFFICE, http://www.uspto.gov/patents/resources/general_info_concerning_patents.jsp (last visited Nov. 26, 2011).

⁶² Robert Cook-Deegan, *From Birth to Death and Bench to Clinic: The Hastings Center Bioethics Briefing Book for Journalists, Policy Makers, and Campaigns*, 69, <http://www.thehastingscenter.org/Publications/BriefingBook/Detail.aspx?id=2174> (last visited Oct. 25, 2011), *cited in* Zard, *supra* note 21.

⁶³ Cook-Deegan, *supra* note 62.

⁶⁴ The Leahy-Smith America Invents Act, H.R. 1249, 120th Cong. (2011) (enacted), *reprinted in* www.uspto.gov/aia_implementation/bills-112hr1249enr.pdf.

Discoveries.”⁶⁵ The first United States Patent Act was established in 1790.⁶⁶ The statute remained unchanged until 1952.⁶⁷ The Act of 1952 provided, “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.”⁶⁸ A patentable invention or discovery must be (1) novel, (2) nonobvious, (3) adequately described or enabled, and (4) claimed by the inventor in clear and definite terms.⁶⁹ The United States Patent and Trademark Office (“USPTO”)⁷⁰ classifies patents into three categories: (1) utility patents, (2) design patents, and (3) plant patents.⁷¹ Gene patents are categorized under utility patents.⁷²

⁶⁵ U.S. CONST. art. I, § 8, *cited in* Zard, *supra* note 21, at 490.

⁶⁶ *1-1 Chisum on Patents §1.01* (LexisNexis 2011). The Patent Act of 1790 “covered ‘any useful art, manufacture, engine, machine, or device, or any improvement therein.’” *Id.* The language was later changed “to read ‘any art, machine, manufacture, or composition of matter, or any new and useful improvement [therein].’” *Id.*

⁶⁷ *Id.* “[T]he Patent Act of 1952 changed the language from ‘art’ to mean ‘process,’ and defined ‘process’ as meaning ‘process, art or method.’ The 1952 Act also defined, particularly redundantly, ‘invention’ as ‘invention or discovery.’” *Id.*

⁶⁸ 35 U.S.C.S. § 101 (LexisNexis 2011), *cited in* Zard, *supra* note 21, at 487, 490.

⁶⁹ *Patents*, UNITED STATES PATENT AND TRADEMARK OFFICE, <http://www.uspto.gov/inventors/patents.jsp#heading-5> (last visited Nov. 9, 2011).

⁷⁰ The United States Patent and Trademark Office (USPTO) is a government agency within the United States Department of Commerce. Zard, *supra* note 21. “[T]he USPTO fulfills the mandate of Article I, Section 8, Clause 8, of the Constitution that the Executive branch “promote the progress of science and the useful arts by securing for limited times to inventors the exclusive right to their respective discoveries.” *The USPTO: Who We Are*, THE UNITED STATES PATENT AND TRADEMARK OFFICE, <http://www.uspto.gov/about/index.jsp> (last visited Jan. 19, 2012). Trademarks are registered by the USPTO based on the Commerce Clause. *Id.* Under the USPTO, the industry in America has flourished. *Id.* “The strength and vitality of the U.S. economy depends directly on effective mechanisms that protect new ideas and investments in innovation and creativity.” *Id.* In addition to registering trademarks and patents, “[t]he USPTO advises the President of the United States, the Secretary of Commerce, and U.S. Government agencies on intellectual property (IP) policy, protection, and enforcement; and promotes the stronger and more effective IP protection around the world.” *Id.* The USPTO headquarters is located in Alexandria, Virginia. *Id.* The office is comprised of more than 8,900 employees including attorneys, analysts, engineers, scientists, and computer specialists. *Id.*

⁷¹ *General Information Concerning Patents*, *supra* note 61; *see also* Zard, *supra* note 21.

⁷² *General Information Concerning Patents*, *supra* note 61. Utility patents are “[i]ssued for the invention of a new and useful process, machine, manufacture, or composition of matter, or a new and useful improvement thereof, it generally permits its owner to exclude others from making, using, or selling the invention for a period of up to twenty years from the date of patent application filing, subject to the payment of maintenance fees. Approximately 90% of the patent documents issued by the PTO in recent years have been utility patents, also referred to as ‘patents for inventions.’” *Types of Patents*, UNITED STATES PATENT AND TRADEMARK OFFICE, <http://www.uspto.gov/web/offices/ac/ido/oeip/taf/patdesc.htm> (last visited Nov. 26, 2011). Design patents are issued for original, new, and ornamental design. *Id.* Design patents “permit[] its owner to exclude others from making, using, or selling the design for a period of fourteen years from the date of patent grant.” *Id.* Plant patents are issued for new,

In general, products from nature are not patentable; however, the USPTO permits genes, and even DNA, to be patentable subject matter.⁷³ The USPTO defines “gene patents” to include “full-length protein encoding gene, a gene fragment, a regulatory region, a cDNA molecule, or a genomic region of unknown function.”⁷⁴ For DNA to be a patentable subject matter, the USPTO requires that it be “isolated, purified, or modified to produce a unique form not found in nature” that has a specific application or use.⁷⁵ Patent protection for utility patents lasts for twenty years from the date of the first application.⁷⁶ To obtain a gene patent inventors are required to “(1) identify novel genetic sequences, (2) specify the sequence’s product, (3) specify how the product functions in nature (i.e. its use), and (4) enable one skilled in the field to use the sequence for that purpose.”⁷⁷ While the USPTO appears to have a system in place to regulate gene patents, legal issues continue to exist that question whether genetic material is patentable subject matter within the scope of 35 U.S.C. § 101.⁷⁸

B. The Common Law Approach to Gene Patents

Much debate has arisen from legislative and judicial recognition of gene patents as patentable subject matter within the scope of 35 U.S.C. § 101. Arguments, both legal and ethical, concerning gene patents have been vocalized since 1980 with

distinct asexually reproduced plants “including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state.” *Id.* Asexually reproduced plants reproduce via fragmentation or division. *Asexual Reproduction*, UCMP BERKLEY, <http://www.ucmp.berkeley.edu/glossary/gloss6/asexual.html> (last visited Jan. 19, 2012). New plants grow by a “separation of parts [from] the original plant.” *Id.* In other words, “an offspring is created by the breakup of a single part of the plant.” *Id.* In essence, a plant clones itself through the process of asexual reproduction, which in some ecosystems is advantageous if genetic material through pollen reproduction is not readily available. *Id.* A plant patent is granted to cover the entire plant. *General Information Concerning Patents*, *supra* note 61. The plant patent term lasts twenty years from the date on which the application was filed in the U.S. *General Information Concerning Patents*, *supra* note 61. Both utility and plant patents are protected for terms of twenty years, while the design patent is only protected for a fourteen-year term. *General Information Concerning Patents*, *supra* note 61.

⁷³ *Genetics and Patenting*, HUMAN GENOME PROJECT INFORMATION, http://www.ornl.gov/sci/techresources/Human_Genome/elsi/patents.shtml#1 (last visited Nov. 9, 2011).

⁷⁴ Zard, *supra* note 21 (citing Gregory C. Ellis, *Emerging Biotechnologies Demand Defeat of Proposed Legislation that Attempts to Ban Gene Patents*, 15 RICH. J.L. & TECH. 1, 7 (2008)).

⁷⁵ *Genetics and Patenting*, *supra* note 73.

⁷⁶ *Patents*, *supra* note 69.

⁷⁷ Zard, *supra* note 21, at 492 (citing *Genetics and Patenting*, *supra* note 73); see also Michele Westhoff, *Gene Patents: Ethical Dilemmas and Possible Solutions*, 20 HEALTH L. 1, 3 (2008).

⁷⁸ See *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

Diamond v. Chakrabarty, and more recently in July, 2011 and again in August, 2012 with the *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*.⁷⁹

1. The Impact of *Diamond v. Chakrabarty*

In *Diamond v. Chakrabarty*, the Supreme Court held that “[a] live, human-made micro-organism [was] patentable subject matter” pursuant to 35 U.S.C. § 101.⁸⁰ In *Chakrabarty*, the defendant Chakrabarty, a microbiologist, filed an application to patent his “invention of ‘a bacterium from the genus *pseudomonas*.’”⁸¹ The “human-made, genetically engineered bacterium” designed by Chakrabarty was “capable of breaking down multiple components of crude oil.”⁸² At that time, the discovery was believed to have made a substantial impact in the treatments used to clean up oil spills because no “naturally occurring bacteria” possesses such capabilities.⁸³

Chakrabarty applied for three different patent claims.⁸⁴ The first claim was a process claim “for the method of producing the bacteria.”⁸⁵ The second claim was “for an inoculum⁸⁶ comprised of a carrier material floating on water,” and the invented bacteria.⁸⁷ The third claim was solely for the invented bacteria.⁸⁸ The patent

⁷⁹ *Chakrabarty*, 447 U.S. at 303 (1980) (holding that a man-made microorganism was patentable under 35 U.S.C.S. § 101); *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 2011 U.S. App. LEXIS 15649 (Fed. Cir. July 31, 2011) (holding that isolated DNA sequences were patentable subject matter); *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303 (2012).

⁸⁰ *Chakrabarty*, 447 U.S. 303 (1980).

⁸¹ *Id.* at 305. The created bacteria contained “two stable energy generating plasmids, each said plasmids provid[ed] a separate hydrocarbon degradative pathway.” *Id.* “Plasmids are hereditary units physically separate from the chromosomes of the cell.” *Id.* at n.1. Chakrabarty discovered the plasmids control of the oil degradation abilities of certain bacteria through previous research with an associate. *Id.* Specifically, Chakrabarty and his associate found plasmids that were capable of degrading two components of oil, camphor and octane. *Id.* In the present case, “Chakrabarty discovered a process by which four different plasmids, capable of degrading four different oil components, could be transferred to and maintained stably in a single *Pseudomonas* bacterium, which itself has no capacity for degrading oil.” *Id.*

⁸² *Id.* at 305.

⁸³ *Id.* “At present, biological control of oil spills requires the use of a mixture of naturally occurring bacteria, each capable of degrading one component of the oil complex. In this way, oil is decomposed into simpler substances which can serve as food for aquatic life. However, for various reasons, only a portion of any such mixed culture survives to attack the oil spill. By breaking down multiple components of oil, Chakrabarty’s micro-organism promises more efficient and rapid oil-spill control.” *Id.* at n.2.

⁸⁴ *Id.* at 305.

⁸⁵ *Id.*

⁸⁶ Inoculums are “cells used in an inoculation, such as cells to start a culture.” *Inoculum*, BIOLOGY-ONLINE, <http://www.biology-online.org/dictionary/Inoculum> (last visited Jan. 17, 2012). In terms of microbiology, inoculation is “the act of introducing [a] microorganism or [a] suspension of microorganisms (e.g. bacteria) into a culture medium. *Id.*

⁸⁷ *Chakrabarty*, 447 U.S. at 306 (1980).

⁸⁸ *Id.*

examiner approved the first two claims, however, the third claim was rejected for two reasons.⁸⁹ First, the patent examiner argued that the “microorganism [was a] ‘product[] of nature.’”⁹⁰ Secondly, the patent examiner argued since the “microorganism [was a] ‘product[] of nature,’” it qualified as a living entity, and therefore was not patentable under 35 U.S.C. § 101.⁹¹ Chakrabarty appealed to the Patent Office Board of Appeals, which was later granted certiorari by the Supreme Court.⁹²

The main question before the Court was whether the microorganism could be classified as a “manufactured” entity or a “composition of matter” within the scope of 35 U.S.C. § 101.⁹³ The Court defined “manufacture” as “the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery.”⁹⁴ “Composition of matter” was defined to include “all compositions of two or more substances and...all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders, or solids.”⁹⁵ The Court did not find “manufacture” and “composition of matter” to be ambiguous terms.⁹⁶ Instead, the Court reasoned that Congress plainly used expansive language to provide a wide scope of patentable objects within the U.S. patent system.⁹⁷ The Court argued the broad terms “fulfill[ed] the [C]onstitutional and statutory goal of promoting ‘the Progress of Science and the useful Arts’ with all the means for the social and economic benefits envisioned by [Thomas] Jefferson.”⁹⁸

⁸⁹ *Id.*

⁹⁰ *Id.*

⁹¹ *Id.*

⁹² *Id.* at 306-07. The Patent Office Board of Appeals found that 35 U.S.C. § 101 did not protect living entities, such as the one created by Chakrabarty. *Id.* at 306. The Court of Customs and Patent Appeals then reversed a prior decision it had made “in *In re Bergy*, 563 F.2d 1031, 1038 (1977), which held that ‘the fact that microorganisms . . . are alive . . . [is] without legal significance’ for purposes of patent law.” *Id.* “*Bergy* involved a patent application for a pure culture of the micro-organism *Streptomyces vellosus* found to be useful in the production of lincomycin, an antibiotic.” *Id.* at n.4. The Supreme Court granted certiorari, and remanded *Bergy* “for further consideration in light of *Parker v. Flook*, 437 U.S. 584.” *Id.* at 306. After, the Court of Customs and Patent Appeals vacated its decision in *Chakrabarty* and consolidated the case with *Bergy* for reconsideration, affirmed the earlier judgments. *Id.* The Supreme Court granted certiorari for both cases, however, *Bergy* was dismissed as moot, leaving only *Chakrabarty*. *Id.* at 307.

⁹³ *Id.* at 307.

⁹⁴ *Chakrabarty*, 447 U.S. at 308 (citing *American Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1 (1931)).

⁹⁵ *Chakrabarty*, 447 U.S. at 308 (citing *Shell Development Co. v. Watson*, 149 F.Supp, 279, 280 (D.C. 1957) (citing 1 A. Deller, *Walker on Patents* § 14, p. 55 (1st ed. 1937))).

⁹⁶ *Chakrabarty*, 447 U.S. at 315.

⁹⁷ *Id.* at 308.

⁹⁸ *Id.* at 315. Thomas Jefferson was a major contributor to the Patent Act of 1793. *Id.* at 308. Jefferson defined patentable subject matter as “any new and useful art, machine, manufacture, or composition of matter, or any new or useful improvement [thereof].”

While it appeared to the Court on the surface that Congress provided a wide scope in regards to the definition of “manufacture” and “composition of matter,” limitations exist that categorize certain entities as non-patentable objects.⁹⁹ Abstract ideas, the laws of nature (i.e. gravity), and physical phenomena are three categories that cannot be patented.¹⁰⁰ While an individual cannot patent the discovery of a new plant or the discovery of a new mineral on Earth, the Court found that the microorganism created by Chakrabarty could not be found in nature, and therefore, fit within the scope of “manufacture” and “composition of matter” under 35 U.S.C. § 101 as patentable subject matter.¹⁰¹

The Supreme Court’s decision in *Chakrabarty* initiated a rush for gene patents within the U.S. patent system by widening the scope of patentable subject matter to allow all substances not found in nature to be patentable under 35 U.S.C. § 101. Since *Chakrabarty*, patents have been permitted for whole genes, segments of genes, and even fragments of DNA.¹⁰² While the USPTO has attempted to establish guidelines for gene patents since the Court’s holding in *Chakrabarty*, issues still arise today that question the very foundation of whether genetic information is patentable as seen in the *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*.¹⁰³

2. The Ongoing Debate of the Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office

In the *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, the U.S. Court of Appeals for the Federal Circuit reversed the decision of the U.S. District Court for the Southern District of New York, holding that isolated DNA is patentable subject matter.¹⁰⁴ Mutations in BRCA1 and BRCA2 genes have been linked to an increased risk of breast and ovarian cancer development in women.¹⁰⁵ Women in the United States have a twelve to thirteen percent chance of developing breast cancer within a lifetime.¹⁰⁶ In the United States, women that have either a BRCA1 or BRCA2 mutation have a fifty to eighty percent chance of developing

Chakrabarty, 447 U.S. at 308 (citing Act of Feb. 21, 1793, § 1, 1 Stat. 319). The 1793 Act “embodied Jefferson’s philosophy that ‘ingenuity should receive a liberal encouragement.’” *Chakrabarty*, 447 U.S. at 308 (citing 5 WRITINGS OF THOMAS JEFFERSON 75-76 (Washington ed. 1871)).

⁹⁹ *Chakrabarty*, 447 U.S. at 309.

¹⁰⁰ *Id.*

¹⁰¹ *Id.* at 309-10.

¹⁰² *Genetics and Patenting*, *supra* note 73.

¹⁰³ *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 2010-1406, 2011 U.S. App. LEXIS 15649 at *54 (Fed. Cir. July 31, 2011).

¹⁰⁴ *Id.* The non-patentability of the isolated DNA segments were not the only issues raised before the court. *Id.* at *8. The plaintiffs “sought a declaration that fifteen claims from the seven patents assigned to Myriad [were] drawn to patent ineligible subject matter under 35 U.S.C. § 101.” *Id.*

¹⁰⁵ *Id.* at *17.

¹⁰⁶ *Id.*

breast cancer and a twenty to fifty percent chance of developing ovarian cancer.¹⁰⁷ Diagnostic testing provides women with information regarding their risk for developing hereditary breast and/or ovarian cancers, which in turn allows women the option to take preventative measures to avoid cancer development.¹⁰⁸ Diagnostic results can also assist in developing proper chemotherapy treatments because some treatments are tailored to effectively treat BRCA1 and BRCA2 related cancers.¹⁰⁹

In the *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, the defendants, Myriad Genetics, Inc. ("Myriad"), discovered that BRCA1 and BRCA2 mutations had a relationship with cancer development.¹¹⁰ Using DNA samples from families afflicted with inherited ovarian cancer and breast cancer, the researchers at Myriad were able to identify individual family members with a particular DNA sequence marker, which facilitated researchers to map the location of the BRCA1 and BRCA2 genes within the human genome.¹¹¹ Once the location of the two genes had been mapped, researchers isolated the exact nucleotide sequences, which allowed Myriad to provide BRCA1 and BRCA2 diagnostic testing for women with breast cancer and ovarian cancer.¹¹²

Myriad filed its first patent application for the isolated BRCA1 DNA and the associated diagnostic methods in August 1994, and the patent, '472 patent, was issued in December 1997.¹¹³ Myriad filed its patent application for the isolated BRCA2 DNA and the associated diagnostic methods in December of 1995, and the patent, '492 patent, was issued in November 1998.¹¹⁴ The district court found that the isolated DNA molecules of BRCA1 and BRCA2, were non-patentable subject matter because the "isolated DNAs [were] not 'markedly different' from native

¹⁰⁷ *Id.*

¹⁰⁸ *Id.*

¹⁰⁹ *Id.* at *18.

¹¹⁰ *Id.*

¹¹¹ *Id.*

¹¹² *Id.*

¹¹³ *Id.*

¹¹⁴ *Id.* at *18-19. Even though Myriad had patents for both the isolated BRCA1 and BRCA2 DNA and subsequent diagnostic methods, Myriad was not the only entity to implement clinical testing with the two strands of DNA. *Id.* at *19. In 1996, the University of Pennsylvania's Genetic Diagnostic Laboratory, which was co-directed by some of the plaintiffs, began providing diagnostic services to women for BRCA1 and BRCA2. *Id.* The Genetic Diagnostic Laboratory was forced to stop providing services based on accusations by Myriad. *Id.* Around the same time, Myriad "initiated several other patent infringement suits against entities providing clinical BRCA testing. *Id.* at *22. Dr. Kazazian was one of the researchers at the Genetic Diagnostic Laboratory at the University of Pennsylvania. *Id.* at *19. Dr. Kazazian, like other researchers, believed that the patents held by Myriad should be found invalid so that he and other researchers could resume testing with BRCA. *Id.* at *23. After the plaintiffs filed suit, Myriad attempted to have the case dismissed alleging that the plaintiffs lacked standing. *Id.* The district court disagreed, and found that the plaintiffs had established standing with the "all circumstances" test. *Id.*

DNAs,” and instead were properly categorized as “products of nature” within the exceptions of 35 U.S.C. § 101 as described in *Chakrabarty*.¹¹⁵

To determine whether the BRCA1 and BRCA2 isolated DNA molecules were patentable subject matter, the court of appeals analyzed the Supreme Court’s decisions in *Chakrabarty* and *Funk Brothers*.¹¹⁶ Both cases involved patents regarding discovered bacteria, however, unlike *Chakrabarty*, the bacteria in *Funk Brothers* was non-patentable because the non-inhibition characteristic that was “newly discovered” was not “markedly different” from the bacteria found in nature.¹¹⁷ Therefore, the distinction between a product of nature and a patentable human-made discovery in correlation with 35 U.S.C. § 101 depends on “the claimed composition’s identity compared with what exists in nature.”¹¹⁸

The court of appeals held that the BRCA1 and BRCA2 isolated sequences were patentable subject matter because the discovered sequences were different from the natural form, and, therefore, did not fall within the exceptions of 35 U.S.C. § 101.¹¹⁹ The court came to this conclusion based on the science and techniques used by the Myriad researchers.¹²⁰ Isolated DNA “is a free-standing portion of a native DNA molecule.”¹²¹ Isolated DNA has been synthesized to consist of a fraction of the naturally occurring DNA molecule.¹²² DNA that has been synthesized or cleaved from native DNA has a “distinctive chemical identity from that possessed by native DNA.”¹²³ In their isolated states, BRCA1 and BRCA2 “are not the same molecules

¹¹⁵ *Id.* at *26. Myriad argued that the district court came to the incorrect conclusion by “(1) misreading Supreme Court precedent as excluding from patent eligibility all ‘products of nature’ unless ‘markedly different’ from naturally occurring ones; and (2) incorrectly focusing not on the differences between isolated and native DNAs, but on one similarity: their informational content.” *Id.* at *47-48. Myriad argued that “an isolated DNA molecule is patent eligible because it is, as claimed, ‘a nonnaturally occurring composition of matter’ with ‘a distinctive name, character and use.’” *Id.* at *48. Myriad outlined that “isolated DNA does not exist in nature, and isolated DNAs, unlike native DNAs [the natural form], can be used as primers and probes for diagnosing cancer.” *Id.* Myriad asserted that the “products of nature” exception not only wasn’t possible to apply because at some level every composition on Earth is comprised of natural materials, but that such a decision would go against the court’s precedents. *Id.* The plaintiffs responded by arguing that the Supreme Court’s precedents establish that “a product of nature is not patent eligible even if, as claimed, it has undergone some highly useful change from its natural form.” *Id.* Plaintiffs asserted that the isolated DNAs were not markedly different from its natural form, and in order to assert a composition as patent eligible, the composition must “have a distinctive name, character, and use, making it ‘markedly different’ from the natural product.” *Id.* at *49.

¹¹⁶ *Id.* at *51.

¹¹⁷ *Id.* at *53.

¹¹⁸ *Id.* at *54.

¹¹⁹ *Id.*

¹²⁰ *Id.* at *56.

¹²¹ *Id.* at *55.

¹²² *Id.*

¹²³ *Id.* at *56. “[T]he BRCA1 gene in its native state resides on chromosome 17, a DNA molecule of around eighty million nucleotides.” *Id.* at *55. “[The] BRCA2 in its native state is located on chromosome 13, a DNA of approximately 114 million nucleotides. In contrast,

as DNA as it exists in the body.”¹²⁴ In other words BRCA1 and BRCA2 are different from the DNA found in nature.¹²⁵ The district court used a “categorical rule” that excluded isolated genes from patent eligibility, which the court of appeals rejected.¹²⁶

In addition to holding the BRCA1 and BRCA2 isolated sequences as patentable subject matter under 35 U.S.C. § 101 based on the test provided by *Chakrabarty* and *Funk Brothers*, the court of appeals also looked to the “longstanding practice” of the USPTO and the Supreme Court.¹²⁷ The USPTO has issued patents for DNA molecules for almost thirty years beginning in the 1980s.¹²⁸ It has been “estimated that the [US]PTO has issued 2,645 patents claiming ‘isolated DNA’” since 1980.¹²⁹ In addition, about 40,000 DNA-related patents have been issued since 2005, twenty percent of which were comprised of gene patents.¹³⁰ Based on these statistics, it is no wonder that the court of appeals’ decision was applauded by the biotechnology industry.¹³¹ As stated by Gerald J. Flattmann Jr., a patent attorney for Paul Hastings in New York City, “It [the court of appeals] adhered to the policy the Patent Office has pursued since the early ‘80s, when the biotech industry was born. Isolated gene patents are the cornerstones of the biotechnology industry.”¹³²

In his New York Times article *Ruling Upholds Gene Patent In Cancer Test*, Andrew Pollack commented that the *Ass’n for Molecular Pathology* might reach the Supreme Court for further ruling.¹³³ The executive director of the Public Patent Foundation, Daniel B. Ravicher, who helped file the lawsuit, “called the decision a partial victory for the plaintiffs[,] [n]oting that one judge dissented on the gene patents.”¹³⁴ Ravicher also commented “the plaintiffs were considering either asking

isolated BRCA1 and BRCA2, with introns, each consist of just 80,000 or so nucleotides. And without introns, BRCA2 shrinks to just 10,200 or so nucleotides and BRCA1 to just around 5,000 nucleotides.” *Id.* An intron is “[p]art of a gene that is initially transcribed into the primary RNA transcript but then removed from it when the exon sequences on either side of it are spliced together.” *Intron*, MEDICINE.NET.COM, <http://www.medterms.com/script/main/art.asp?articlekey=4026> (last visited Jan. 18, 2012). An intron is also known as an intervening sequence. *Id.*

¹²⁴ *Ass’n Molecular Pathology*, 2011 U.S. App. LEXIS 15649 at *56.

¹²⁵ *Id.*

¹²⁶ *Id.* at *60.

¹²⁷ *Id.* at *64.

¹²⁸ *Id.* at *65.

¹²⁹ *Id.*

¹³⁰ *Id.*

¹³¹ Andrew Pollack, *Ruling Upholds Gene Patent in Cancer Test*, N.Y. TIMES, July 29, 2011, http://www.nytimes.com/2011/07/30/business/gene-patent-in-cancer-test-upheld-by-appals-panel.html?_r=1 (last visited Jan. 18, 2012).

¹³² *Id.*

¹³³ *Id.*

¹³⁴ *Id.*

the entire appellate court to rehear the gene patenting aspects of the case or appealing to the Supreme Court.”¹³⁵

A petition of certiorari was filed from the July 29, 2011 court of appeals opinion, in which the Supreme Court of the United States granted the petition, vacated the decision, and remanded the case back to the court of appeals to be reconsidered in the light of the Supreme Court’s decision in *Mayo Collaborative Services v. Prometheus Inc.* (“*Mayo*”).¹³⁶ The Supreme Court’s decision in *Mayo* “tightened rules on medical-testing patents.”¹³⁷ Specifically, the court “invalidated a pair of ‘method’ patents that claimed a process for setting dosages.”¹³⁸ In the remanded appeal, the court of appeals made a decision, which decided the issues on the original appeal and evaluated the effect of *Mayo* on the original issues.¹³⁹ On remand, the court of appeals reversed the district court’s holding “that Myriad’s composition claims to ‘isolated’ DNA molecules cover patent-ineligible products of nature under § 101 because each of the claimed molecules represents a nonnaturally occurring composition of matter.”¹⁴⁰ Shortly after the court of appeals remanded decision, the Supreme Court granted certiorari to establish whether human genes are patentable subject matter.¹⁴¹

While *Chakrabarty* and the *Ass’n for Molecular Pathology* establish the constitutional concerns regarding gene patents that the judicial system has so far overturned, society has become increasingly split in its opinions of whether gene patents should be permissible within the U.S. patent system.

¹³⁵ *Id.*

¹³⁶ *Ass’n for Molecular Pathology v. U.S. Patent and Trademark Office*, 689 F.3d 1303, 1308 (Fed. Cir. Aug. 16, 2012).

¹³⁷ Brent Kendall, *Court to Decide Whether Genes Can Be Patented*, WALL ST. J., July 20, 2012, at A3.

¹³⁸ *Id.* “Judge Kimberly Moore, who penned a concurring opinion for the Federal Circuit last year, wrote that the Myriad patents ‘raise substantial moral and ethical issues related to awarding a property right to isolated portions of human DNA—the very thing that makes us humans, and not chimpanzees.’ But she also said that the U.S. Patent and Trademark Office has allowed patents on the DNA sequences for decades and that disturbing the industries long-held expectations risked impeding innovation.” *Id.*

¹³⁹ *Ass’n Molecular Pathology*, 689 F.3d at 1308.

¹⁴⁰ *Id.* at 1308-09. The court “also reversed the district court’s decision that Myriad’s method claim to screening potential cancer therapeutics via changes in cell growth rates of transformed cells is directed to a patent-ineligible scientific principle.” *Id.* Lastly, the court affirmed the district court’s decision that the claims that “comparing” and “analyzing” procedures for DNA sequences were patent ineligible because there were no transformative steps. *Id.*

¹⁴¹ *Id.* at 1308. On June 13, 2013, the Supreme Court of the United States unanimously established that human genes may not be patented. Adam Liptak, *Justices, 9-0, Bar Patenting Human Genes*, N.Y. TIMES, June 13, 2013, http://www.nytimes.com/2013/06/14/us/supreme-court-rules-human-genes-may-not-be-patented.html?_r=0 (last visited June 23, 2013). Justice Clarence Thomas wrote for the court that “‘Myriad did not create anything...[t]o be sure, it found an important and useful gene, but separating the gene from its surrounding genetic material is not an act of invention.’” *Id.* This ruling “drew a sharp distinction between DNA that appears in nature and synthetic DNA created in the laboratory.” *Id.*

3. Society's Split on Gene Patents

Since the 1980s with the Supreme Court's holding in *Chakrabarty*, a split has developed within society's view regarding the patentability of genetic material. Proponents argue that gene patents (1) reward researchers for their work and supply monetary rewards to further their research, (2) "provide a monopoly to [] inventor[s]" in turn "prohibiting competitors from making, using, or selling [] patented discover[ies]," (3) prevent "wasteful duplications," (4) force science to reach "into new, unexplored areas," and (5) reduce innovative secrecy and promote communication between researchers.¹⁴² Opponents argue that gene patents (1) impede on scientific research, (2) allow researchers to patent a part of nature, and (3) allow monopolies.¹⁴³ The themes argued by both sides of the debate can be categorized into three sections: (1) the issues surrounding the creation of monopolies, (2) the issues concerning the affects on scientific research, and (3) the issues concerning patenting a part of "nature."

i. Monopolies

Proponents of patenting genetic material argue that gene patents allow researchers to monopolize their discoveries, which provides monetary and property rewards.¹⁴⁴ "Patents facilitate genetic research by encouraging investment in what would otherwise be a risky financial investment."¹⁴⁵ The biotechnology industry, as a whole, is a strong proponent for gene patents because a large portion of profit comes from "intellectual and financial investments," which in turn facilitate research.¹⁴⁶ Individuals challenging gene patents maintain that while monopolies may be an asset to large biotechnological corporations, monopolies hurt smaller corporations.¹⁴⁷ Proponents for gene patents, however, disagree and argue that small biotechnological corporations gain the same benefits as larger biotechnological corporations.¹⁴⁸ Regardless of size, if gene patents are barred, corporations that do not have the sources to fund research will lose the ability to attract investors, ultimately resulting in delays in research or completely preventing research from occurring.¹⁴⁹

While monopolies created by gene patents arguably assist in funding future research, opponents argue that monopolies raise the cost of diagnostic testing that could be reduced if biotechnological companies did not hold monopolies over their patents.¹⁵⁰ For example, Myriad Genetics, Inc. holds the patents for both BRCA1

¹⁴² *Genetics and Patenting*, *supra* note 73.

¹⁴³ *Id.*

¹⁴⁴ *Id.*

¹⁴⁵ Zard, *supra* note 21, quoting James Bradshaw, *Gene Patent Policy: Does Issuing Gene Patents Accord with the Purposes of the U.S. Patent System?*, 37 WILLIAMETTE L. REV. 637, 653 (2001).

¹⁴⁶ Zard, *supra* note 21.

¹⁴⁷ *Genetics and Patenting*, *supra* note 73.

¹⁴⁸ Zard, *supra* note 21.

¹⁴⁹ Zard, *supra* note 21.

¹⁵⁰ Pollack, *supra* note 131.

and BRCA2 genes.¹⁵¹ Myriad, being the only entity permitted to use the genes, charges more than \$3,000 for its diagnostic test to determine whether an individual is at risk for breast or ovarian cancer.¹⁵² While this is a strong argument against monopolies created by gene patents, in essence, all patents create a monopoly due to the basic concepts patents are based upon.¹⁵³

¹⁵¹ Pollack, *supra* note 131.

¹⁵² Pollack, *supra* note 131. While Myriad Genetics retained its monopolies over the BRCA1 and BRCA2 genes, it is only a matter of time before Myriad has challenges to face again. Andrew Pollack, *Despite Gene Patent Victory, Myriad Genetics Faces Challenges*, THE N.Y. TIMES (Aug. 24, 2011), http://www.nytimes.com/2011/08/25/business/despite-gene-patent-victory-myriad-genetics-faces-challenges.html?_r=1&pagewanted=all. Experts believe that the expensive testing will become incompetent and will be “outmoded, complete, and too costly” as technological breakthroughs continue to occur. *Id.* Mary-Claire King, a professor of genome sciences and medicine at the University of Washington argues that “Science has moved beyond what these folks do. It’s not good for the science and it’s not good for the patients and their clinicians if they cannot have the most complete, up-to-date information.” *Id.* The new techniques used with DNA sequences are faster and cheaper than the technology that Myriad developed in the 1990s. *Id.* Soon, for the same price that Myriad charges for just two genes, individuals will be able to have their entire genome sequence mapped -- about 22,000 genes. *Id.* Myriad executives counter that the company is preparing for the technological changes. *Id.* Executives also point out that the “company’s patent protection should last until at least 2018,” which will give the company the opportunity to adopt and diversify the latest technology. *Id.* The company announced plans that it intends to rely less on patents, and instead rely on trade secrets. *Id.* Myriad has done the most in terms of testing with BRCA1 and BRCA2 genes, and it is more than likely that Myriad knows “which of the thousands of possible mutations in the two genes actually raise the risk of cancer.” *Id.* “Myriad used to share such information with a public database maintained by the National Institutes of Health, and it cooperated with academic scientists trying to analyze the mutations [; however,] a few years ago, the company quietly stopped contributing and cooperating, in favor of building its own database.” *Id.* In 2006, Myriad developed a supplemental test, known as the Comprehensive BRAC Analysis, that corrected issues from its previous test. *Id.* The supplemental test cost \$700, but insurers do not cover the cost, leaving many women without the opportunity to obtain the test. *Id.* “More than 200 doctors, genetic counselors and other health care professionals have signed an open letter to Myriad urging it to incorporate the supplemental testing into the main test.” *Id.* For example:

Kathleen Maxian says that if that had been done earlier, she might not be fighting for her life against ovarian cancer. Her sister developed breast cancer at age 40 about five years ago, but tested negative for mutations on Myriad’s main test. She was not offered the supplemental test. Two years ago, Ms. Maxian developed ovarian cancer. It turned out that both she and her sister had genetic alterations that were detectable only by the supplemental test. ‘If my sister had had that test and had gotten a positive result, I would have gone to a genetic counselor and have been tested,’ said Ms. Maxian, who is 49 and lives in Pendleton, N.Y., near Buffalo. She would then have had the option of having her ovaries removed to avoid getting ovarian cancer. ‘I don’t want to see this happen to anyone else,’ she said. ‘Women should have this test.’

Id.

¹⁵³ Gene Quinn, *Patent Misuse, Exploring the Basics*, IPWATCHDOG (March 11, 2013), <http://www.ipwatchdog.com/2011/11/18/patent-misuse-exploring-the-basics/id=20460/>

In *Kewanee Oil Co. v. Bicron Corp.*, the Supreme Court justified the purpose of patents “to provide incentives for inventiveness and research efforts.”¹⁵⁴ It was the intentions of the Framers’ to grant temporary exclusive rights to researchers for their discoveries to further promote research and development and allow rewards for researchers.¹⁵⁵ Monopolies are inevitable with the use of not only gene patents but patents in general. Monopoly can be defined as an “exclusive ownership through legal privilege.”¹⁵⁶ A patent as defined by Merriam-Webster, is “a: a writing securing for a term of years the exclusive right to make, use, or sell an invention [or] b: the monopoly or right so granted.”¹⁵⁷ By granting an individual the exclusive right over their discovery, a monopoly is automatically created. Therefore if opponents to gene patents wish to eliminate the monopolies created by patents in entirety, the concept of patents would have to be eliminated, which goes against the intentions of the Framers’.

ii. *The Effects on Science and Genetic Research*

Proponents of gene patents argue that scientific research and discoveries are amplified with the use of gene patents, while opponents argue that gene patents place a significant hold and block on the collaborative basis for which scientific research occurs.¹⁵⁸ Both sides of the debate are correct in their analysis; however, both aspects are needed to further promote scientific research and scientific breakthroughs. This concept will be further analyzed in Part IV of this Note.

iii. *Patenting an Aspect of Nature*

Whether genetic material can be categorized as patentable subject matter in connection with 35 U.S.C. § 101, has been a topic of much debate since the 1980s. *The Ass’n for Molecular Pathology* is the most recent case that demonstrates the judicial stance on gene patents as patentable subject matter within scope of 35 U.S.C. § 101.¹⁵⁹ With both the courts and the USPTO support of gene patents for almost thirty years, it is unlikely that the norm will change.¹⁶⁰ In its recent grant of certiorari in the *Ass’n for Molecular Pathology*, the Supreme Court will likely affirm the court of appeals decision and permit isolated DNA sequences as patentable

¹⁵⁴ Zard, *supra* note 21 (citing *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480-81 (1974)).

¹⁵⁵ Zard, *supra* note 21 (citing Michele Westhoff, *Gene Patents: Ethical Dilemmas and Possible Solutions*, 20 HEALTH L. 1, 6 (2008) (citing Carol Schneider et al., *Patenting Life: A View from the Constitution and Beyond*, 24 WHITTIER L. REV. 385, 387-88 (2002))).

¹⁵⁶ *Monopoly*, MERRIAM-WEBSTER, <http://www.merriam-webster.com/dictionary/monopoly> (last visited Jan. 18, 2012).

¹⁵⁷ *Patent*, MERRIAM-WEBSTER, <http://www.merriam-webster.com/dictionary/patent> (last visited Jan. 18, 2012).

¹⁵⁸ *Genetics and Patenting*, *supra* note 73.

¹⁵⁹ *See Ass’n for Molecular Pathology v. U.S. Patent and Trademark Office*, 689 F.3d 1303, 1308 (Fed. Cir. Aug. 16, 2012).

¹⁶⁰ Daniel J. Kevles, *Can They Patent Your Genes?* <http://www.nybooks.com/articles/archives/2013/mar/07/can-they-patent-your--genes/?pagination=false&printpage=true> (last visited March 7, 2013).

subject matter as it has been the protocol since *Chakrabarty*.¹⁶¹ Changing the standard by which scientists and the biomedical industry have come accustomed to since 1980 and the holding in *Chakrabarty*, a loss for *Myriad* could significantly hurt the biomedical industry and scientific progress.¹⁶²

The purpose of this Note is not to analyze whether genetic material is patentable subject matter under 35 U.S.C. § 101. This Note is written following the latest judicial decision in *Ass'n for Molecular Pathology*, in addition to the historical stance the USPTO and the courts have followed, in finding that genetic material is patentable subject matter under 35 U.S.C. § 101. The remainder of this Note addresses whether the new Leahy-Smith America Invents Act (“AIA”) implements the expressed societal concerns surrounding gene patent regulations, and examines changes that need to be implemented to promote scientific research and collaboration that will foster more timely results in diagnostic technologies and treatments.

IV. LEAHY-SMITH AMERICA INVENTS ACT (“AIA”)

The AIA is the first major reform to the United States patent law system since 1952.¹⁶³ The AIA, while narrow in scope, keeps the basic structure of the U.S. patent system by implementing numerous changes to promote efficiency and structure.¹⁶⁴ While the AIA does promote new changes and advances in the U.S. patent system, the AIA does not address the concerns established by critics of gene patents that grew from the Patent Act of 1952 and the recent explosion in genetic research.¹⁶⁵ Before criticizing the AIA for neglecting to implement procedures and regulations specifically designed for gene patents, a thorough overview on the new legislation must be provided.

The AIA harmonizes the U.S. patent system with other patent systems established in Europe and other countries by implementing a first-inventor-to-file system (“FITF”).¹⁶⁶ The AIA also addresses issues that have negatively impacted the U.S. patent system. The AIA amends the “joinder standard for joining defendants in a patent infringement action and eliminat[es] *qui tam* false marking actions entirely.”¹⁶⁷ In addition to implementing the FITF system, the AIA also promotes

¹⁶¹ Kendall, *Supra* note 137.

¹⁶² Kendall, *Supra* note 137.

¹⁶³ Erick Bensen, *Erick E. Bensen on the America Invents Act*, 2011 EMERGING ISSUES 5900 (LexisNexis 2011).

¹⁶⁴ The Leahy-Smith America Invents Act, H.R. 1249, 120th Cong. (2011) (enacted), reprinted in www.uspto.gov/aia_implementation/bills-112hr1249enr.pdf.

¹⁶⁵ *Id.*

¹⁶⁶ 1 PAT. L. FUNDAMENTALS § 1:37 (West 2013); see John E. Schneider, *Leahy-Smith America Invents Act – Patent Reform 2011 is Finally Here*, 2011 EMERGING ISSUES 5929 (LexisNexis 2012).

¹⁶⁷ John E. Schneider, *supra* note 166. Prior to the implementation of the AIA, “any individual could bring a *qui tam* action on products that [were] mismarked as covered by a patent,” under 35 U.S.C. § 292(a). Zahra Hayat, Esq. at. el., *How the America Invents Act will change patent litigation*, WESTLAW JOURNAL INTELLECTUAL PROPERTY, Nov. 18, 2011, http://newsandinsight.thomsonreuters.com/Legal/Insight/2011/11_-_November/How_the_America_Invents_Act_will_change_patent_litigation/ (last visited Jan. 19, 2012). The statute allotted for fines of \$500 “per offense” which in the end could add up to millions of dollars if

faster patent processing, implements a new derivation proceeding, and revamps the post-patent review proceedings.¹⁶⁸

A. Patent Processing

1. First-Inventor-to-File

A major change the AIA makes to the U.S. patent system is the conversion from a first-to-invent system to a first-inventor-to-file (“FITF”) system.¹⁶⁹ Changing the U.S. patent system to the FITF system harmonizes the U.S. patent system with the European patent system, giving American inventors more protection abroad by making the patent process more efficient, predictable, and in accord with foreign guidelines.¹⁷⁰ The adoption of the FITF system will be officially implemented eighteen months from the date President Obama signed the AIA into law.¹⁷¹ During this eighteen-month period, the AIA calls for two studies to be performed.¹⁷² The first study is designed to look into the effect the FITF system will have on small businesses, while the second study determines whether the U.S. should implement a “prior user rights.”¹⁷³ The delay will allow Congress to assess the findings of the two studies to determine if and what change need to be made to the FITF system.¹⁷⁴

i. Changes Made by the FITF System

The AIA changes the language of the old first-to-invent system to the FITF system by amending the language to state “that a person shall be entitled to a patent unless it was made available to the public, sold, or offered for sale anywhere in the world, or patented or described in a publication before the effective filing date of the claimed invention.”¹⁷⁵ With the new system, patents and published patent applications become “prior art” on the “effective filing date” of the patent or patent application.¹⁷⁶ “Effective filing date” is defined by the AIA “as the actual filing date of an application or the filing date of the earliest application for which the patent or

a product was popular among the public. *Id.* Under the new regulations implemented by the AIA, *only* the United States government will be able to sue for damages for false marking. *Id.* “Private parties will be entitled only to compensatory damages based on ‘competitive injury flowing from the false marking.’” *Id.* This new legislation will apply to pending cases, as well as on cases that were commenced on or after the enactment of the AIA. *Id.* It is likely, that because of these new regulations, that false marking cases will become rare in the future. *Id.*

¹⁶⁸ John E. Schneider, *supra* note 166.

¹⁶⁹ The Leahy-Smith America Invents Act, H.R. 1249, 120th Cong. (2011) (enacted), reprinted in www.uspto.gov/aia_implementation/bills-112hr1249enr.pdf

¹⁷⁰ Bensen, *supra* note 163.

¹⁷¹ John E. Schneider, *supra* note 166.

¹⁷² John E. Schneider, *supra* note 166.

¹⁷³ John E. Schneider, *supra* note 166. Both studies must be completed within a year. John E. Schneider, *supra* note 166.

¹⁷⁴ John E. Schneider, *supra* note 166.

¹⁷⁵ John E. Schneider, *supra* note 166.

¹⁷⁶ John E. Schneider, *supra* note 166.

application is entitled for that invention.”¹⁷⁷ The implementation of a FITF system will end the need for expensive discovery and litigation over priority dates because inventors will now be able to establish priority dates by filing an inexpensive, simple application.¹⁷⁸

ii. Exceptions to the FITF System

The FITF system has two main exceptions.¹⁷⁹ The first exception entitles inventors “to a one year grace period for disclosures made by the inventor or by one who obtained the disclosed information from the inventor.”¹⁸⁰ The AIA, however, does not define the term “disclosure.”¹⁸¹ The definition will likely be left to the courts to determine, as it will more than likely be a topic of early-litigated actions.¹⁸² The second exception excludes “narrow categories of patents and published applications that encompass [an] inventor’s own work.”¹⁸³ These narrow categories incorporate patents and applications that release information acquired by the inventor, information that was described in a publication by the inventor, or information that was owned or assigned to a common owner.¹⁸⁴ An example of work that may fall within the second exception would be information developed from a joint research agreement between two inventors.¹⁸⁵ In addition to changing the patent system to FITF system, the AIA also changes the rights of third parties.

2. Submissions by Third Parties

Before the AIA, under the former patent legislation, third parties had limited input with the patent application process.¹⁸⁶ Now, under the AIA, “any third party may submit prior art for consideration and inclusion in the record of a patent application.”¹⁸⁷ Prior art can be defined to be “any patent, published patent application, or other printed publication of potential relevance to the examination of the application.”¹⁸⁸ A submission of prior art by a third party must be made in

¹⁷⁷ John E. Schneider, *supra* note 166.

¹⁷⁸ The Leahy-Smith America Invents Act, H.R. 1249, 120th Cong. (2011) (enacted), reprinted in www.uspto.gov/aia_implementation/bills-112hr1249enr.pdf.

¹⁷⁹ John E. Schneider, *supra* note 166. The AIA does not address how individuals can prove that one of the exceptions of the FITF system applies to their situation. Schneider, *supra* note 166. “Presumably declarations or affidavits can be used to establish that a reference is not prior art or that the information disclosed was obtained by the inventor.” Schneider, *supra* note 166.

¹⁸⁰ John E. Schneider, *supra* note 166.

¹⁸¹ John E. Schneider, *supra* note 166.

¹⁸² John E. Schneider, *supra* note 166.

¹⁸³ John E. Schneider, *supra* note 166.

¹⁸⁴ John E. Schneider, *supra* note 166.

¹⁸⁵ John E. Schneider, *supra* note 166.

¹⁸⁶ 1 PAT. L. FUNDAMENTALS § 1:37 (West 2013).

¹⁸⁷ *Id.*

¹⁸⁸ *Id.*

writing within six months of the application publication.¹⁸⁹ The submission “must set forth a concise description of the asserted relevance of each submitted document.”¹⁹⁰ Along with the rights of third parties being recognized, the AIA also changed the means by which an applicant inventor can make an oath.

3. Inventors Oath

Pursuant to the prior patent legislation, “applicants were required to provide an oath or declaration of each applicant inventor stating that the applicant ‘believed himself to be the original and first inventor of the process, machine, manufacture, or composition of matter, or improvement thereof for which he solicits a patent.’”¹⁹¹ Now, under the AIA, a modification in the provision has been amended for applicant inventors that are “deceased, under legal capacity, can not be found after diligent effort, or [are] under obligation to assign the invention but [have] refused to make oath or declaration.”¹⁹² In such circumstances, the AIA has given the option for an applicant inventor to substitute a statement in lieu of an inventor oath or declaration.¹⁹³ While making some positive changes, the AIA has also prohibited a few means of former patentable subject matter.

4. Tax Strategies with Patent Applications

Under former patent legislation, individuals could obtain patents for “tax strategies for lowering or reducing tax liability.”¹⁹⁴ Under the AIA, such patent applications are prohibited, “by defining such an invention, including any strategy for reducing, avoiding, or deferring tax liability...as deemed insufficient to differentiate a claimed invention from the prior art.”¹⁹⁵

5. Human Organisms

Under former U.S. patent legislation, it was the USPTO’s policy to reject patent applications or claims regarding human organisms.¹⁹⁶ The AIA has codified this policy, formerly known as MPEP § 2105, by establishing that “human organisms [were] not patentable subject matter.”¹⁹⁷ An organism is “[a]n individual living thing that can react to stimuli, reproduce, grow, and maintain homeostasis.”¹⁹⁸ Pursuant to

¹⁸⁹ *Id.*

¹⁹⁰ *Id.*

¹⁹¹ *Id.*

¹⁹² *Id.* (quoting 35 U.S.C.A. § 115).

¹⁹³ *Id.*

¹⁹⁴ *Id.*

¹⁹⁵ *Id.*

¹⁹⁶ *Id.*

¹⁹⁷ *Id.* (Pursuant to MPEP § 2105, “[i]f the broadest reasonable interpretation of the claimed invention as a whole encompasses a human being, then a rejection under 35 U.S.C. § 101 must be made indicating that the claimed invention is directed to nonstatutory subject matter.”)

¹⁹⁸ *Organism*, BIOLOGY ONLINE, <http://www.biology-online.org/dictionary/Organism> (last visited Feb. 20, 2013).

the definition of organism, the prohibition on human organism patents by the AIA does not include gene patents because (1) genes are merely a sequence of nucleotides (a segment of DNA) found on a chromosome that is *part* of an organism, and (2) genes cannot react to stimuli, grow, or reproduce.¹⁹⁹ Thus, gene patents are still untouched by the prohibitions established by the AIA.

6. Prioritized Examination

Under the AIA, the USPTO provides a “prioritized examination” option, in which individuals can purchase “prioritized examination” upon filing a patent application.²⁰⁰ An application with “prioritized examination” gives an application “special status” in order for the application to be advanced through the USPTO’s examination process.²⁰¹ This “special status” allows applications to be processed at a faster rate so that a final disposition can be granted within twelve months of the priority examination date.²⁰² Status can be granted through one of the following:

- “[m]ailing of a notice of allowance;”²⁰³
- “mailing of a final Office action;”²⁰⁴
- “filing of a notice of appeal;”²⁰⁵
- “completion of examination as defined in 37 C.F.R. 41.102;”²⁰⁶
- “filing of a request for continued examination; or”²⁰⁷
- “abandonment of the application”²⁰⁸

In addition to a fee for prioritized examination, applicants still must pay the ordinary filing fee, search fee, and other miscellaneous fees.²⁰⁹ One of the goals of the AIA is to implement an overall faster patent process.

7. Faster Patent Processing

The AIA has a twelve-month guarantee for patent processing, which significantly decreases patent processing from an average of three years, and thus aids in the reduction of the present patent backlog.²¹⁰ Currently, the backlog has been reduced

¹⁹⁹ *Gene*, BIOLOGY ONLINE, <http://www.biology-online.org/dictionary/Gene> (last visited Feb. 20, 2013).

²⁰⁰ 1 PAT. L. FUNDAMENTALS § 1:37 (West 2013).

²⁰¹ *Id.*

²⁰² *Id.*

²⁰³ *Id.*

²⁰⁴ *Id.*

²⁰⁵ *Id.*

²⁰⁶ *Id.*

²⁰⁷ *Id.*

²⁰⁸ *Id.*

²⁰⁹ *Id.*

²¹⁰ *President Obama Signs America Invents Act*, *supra* note 19.

to 680,000 from 750,000 despite a 4% increase in filings.²¹¹ Horacio Gutierrez, Microsoft's deputy general counsel for intellectual property and licensing, commented that the changes the AIA makes "will ensure that innovators in our troubled economy can benefit from a predictable and rational patent system, with new tools to eliminate patents that should not have been issued and to speed the processing of patents that should be issued."²¹² In connection with implementing the FITF system and decreasing the patent processing time period, the AIA also establishes a new protective proceeding for inventors.

8. Derivation Proceedings

The AIA's implementation of the derivation proceedings eliminates the U.S. patent systems' previously used process of interferences.²¹³ Derivation proceedings determine whether a patented invention was derived from the work of another patented invention or patent application.²¹⁴ These proceedings can be heard in two different systems depending on the particular issues.²¹⁵ If the conflict arises between two different patents, the hearing will proceed in district court.²¹⁶ If the conflict arises between a patent and an application or two different applications, the proceedings will occur at the USPTO in front of the Patent Trial and Appeal Board.²¹⁷ In addition to providing changes with filing, processing and initial legal proceedings, the AIA also implements new plans for post-patent proceedings.²¹⁸

B. Post-Patent Proceedings and Review

The AIA brings numerous changes to the U.S. patent systems standard of review for granted patents.²¹⁹ While the AIA retains reissue and Ex Parte Reexamination proceedings enacted from previous patent acts, it replaces the Inter Partes Reexaminations with the Inter Partes Review, and adds two additional proceedings, the Post Grant Review and the Supplemental Examination proceedings, to the U.S. patent system.²²⁰

²¹¹ *President Obama Signs America Invents Act*, *supra* note 19.

²¹² Kathleen Hunter & Susan Decker, *Senate OKs Revamp of U.S. Patent System*, PHILLY.COM (Sept. 9, 2011), http://articles.philly.com/2011-09-09/business/30135097_1_patent-system-trademark-office-johnson-johnson.

²¹³ John E. Schneider, *supra* note 166.

²¹⁴ John E. Schneider, *supra* note 166.

²¹⁵ John E. Schneider, *supra* note 166.

²¹⁶ John E. Schneider, *supra* note 166.

²¹⁷ John E. Schneider, *supra* note 166.

²¹⁸ John E. Schneider, *supra* note 166.

²¹⁹ John E. Schneider, *supra* note 166.

²²⁰ John E. Schneider, *supra* note 166.

1. Inter Partes Review

Congress introduced the inter partes reexamination principle in the Reexamination Act in 1980.²²¹ The purpose of the inter partes reexamination principle was to “strengthen investor confidence in the certainty of patent rights by establishing a system of administrative reexamination of doubtful patents.”²²² While the new inter partes review upholds the baseline of the previous process, the new proceeding changes when a petition for review can be filed.²²³ Under the AIA, a petition for review can be filed nine months after a patent has been granted or if a post grant review has commenced, a petition can be filed after a decision has been reached.²²⁴ The inter partes review also implements a new standard of review, which analyzes whether a reasonable likelihood exists that the petitioner will prevail in respect to one of the challenged claims.²²⁵ In addition, the AIA also seeks to speed up the inter partes review process, an underlying theme seen throughout the AIA.²²⁶ Similar to the inter partes review, the post grant review system implemented by the AIA seeks to challenge the validity of patents.²²⁷

2. Post Grant Review

The AIA created a new proceeding, post grant review (“PGR”), “where third parties are able to challenge the validity and scope of an issued patent.”²²⁸ Prior to the AIA, individuals were limited to challenge patents solely based on obviousness and novelty, and based upon “prior patents or printed publications.”²²⁹ Under PGR, an individual can challenge a patent on any ground of patentability and is not limited to prior art patents and printed publications.²³⁰ PGR can be implemented in two circumstances.²³¹ First, PGR can be implemented if the information in the petition demonstrates that one of the challenged claims is more likely than not patentable.²³² Secondly, PGR can be implemented if the petition raises a novel or unsettled legal question that is important to other similar patents and patent applications.²³³ A PGR must be filed within nine months of the issuance of the patent or “issuance of a

²²¹ Roger Shang, *Inter Partes Reexamination and Improving Patent Quality*, 7 NW. J. TECH. & INTELL. PROP. 185, 186 (2009).

²²² *Id.* (quoting *Kaufman v. Lantech*, 807 F.2d 970, 976 (Fed. Cir. 1986) (citing H.R. REP. NO. 96-1307, pt. 1, at 3-4 (1980))).

²²³ John E. Schneider, *supra* note 166.

²²⁴ John E. Schneider, *supra* note 166.

²²⁵ John E. Schneider, *supra* note 166.

²²⁶ John E. Schneider, *supra* note 166.

²²⁷ John E. Schneider, *supra* note 166.

²²⁸ 1 Pat. L. Fundamentals § 1:37 (West 2013).

²²⁹ *Id.*

²³⁰ *Id.*

²³¹ John E. Schneider, *supra* note 166.

²³² John E. Schneider, *supra* note 166.

²³³ John E. Schneider, *supra* note 166.

broadening reissue.”²³⁴ A petitioner must chose between challenging a patent with either the USPTO or the courts.²³⁵ The AIA does not establish specific rules concerning the “rules of conduct” for the PGR; instead the AIA left the USPTO the responsibility of developing the rules.²³⁶ In addition to creating the PGR proceedings, the AIA also establishes Supplemental Examination proceedings.

3. Supplemental Examination

Supplemental examination allows a patent owner the ability to address any validity issues that may have been uncovered after the patent had been granted.²³⁷ This process begins after a patent owner files a petition with the USPTO “raising at least one new substantial question of patentability.”²³⁸ If the USPTO finds that the owner of a patent has raised a substantial question of patentability, then the patent will be examined under the procedures for ex parte reexamination.²³⁹ Ex parte reexamination provides patent owners and third parties the ability to request the USPTO to reconsider patents that are based on pre-existing technology that was not initially reviewed.²⁴⁰ The USPTO only reexamines patents that propose a new substantial question that needs to be reviewed.²⁴¹ While making substantial changes and improvements to the U.S. patent system with the implementation of the FITF system, faster patent processing, the creation of derivation proceedings, and the reworking of the post patent processing, the AIA does not address or implement new guidelines specifically designed to regulate gene patents.

C. Litigation

1. Defenses to Infringement Cases

Under the AIA, the “prior use” defense, which originally was only permitted for business method patent cases, is expanded as a defense for patent infringement for all patent types.²⁴² The prior use defense prohibits patent infringement²⁴³ claims against individuals that show that (1) “they acted in good faith;” (2) “they actually reduced the subject matter of a patented invention to practice at least one year before the patentee filed its patent application;” and (3) “they commercially used that subject matter before the patentee filed its patent application.”²⁴⁴

²³⁴ John E. Schneider, *supra* note 166.

²³⁵ John E. Schneider, *supra* note 166.

²³⁶ John E. Schneider, *supra* note 166.

²³⁷ John E. Schneider, *supra* note 166.

²³⁸ John E. Schneider, *supra* note 166.

²³⁹ John E. Schneider, *supra* note 166.

²⁴⁰ Robert A. Clarke, *Reexamination at the USPTO*, THE UNITED STATES PATENT AND TRADEMARK OFFICE, http://www.uspto.gov/patents/law/exam/presentation/reexam_24may2010.ppt (last visited Jan. 19, 2012).

²⁴¹ *Id.*

²⁴² 1 PAT. L. FUNDAMENTALS § 1:37 (West 2013).

²⁴³ *Id.*

²⁴⁴ *Id.*

2. Joinder of Parties in Infringement Litigation Cases

While expanding the scope of infringement cases, the AIA limits the number of joinder of parties in infringement cases.²⁴⁵ A plaintiff that is related to the parties in a single suit can only join lawsuits filed on or after the date of enactment.²⁴⁶ This limit is implemented to require separate lawsuits to allow defendants to have an easier means to seek venue transfer.²⁴⁷

3. Venue

Under the AIA, venue for patent litigation involving the USPTO has been changed.²⁴⁸ Previously, patent litigation cases were filed in the U.S. District Court for the District of Columbia.²⁴⁹ Now, pursuant to the AIA, cases are to be filed in the U.S. District Court of the Eastern District of Virginia,²⁵⁰ specifically for cases filed under the following sections:

- “Section 32 related to disciplinary proceedings against patent practitioners;”²⁵¹
- “Section 145 related to civil actions to obtain a patent;”²⁵²
- “Section 154(b) related to patent term adjustment;”²⁵³ and
- “Section 146 related to civil actions in interference cases actions against a foreign patent owner”²⁵⁴

In addition to changing venue for particular patent cases, the AIA also narrowed the scope of false marketing cases.

4. Advice of Counsel Defense

Under the AIA, if a defendant in a patent infringement lawsuit fails to obtain advice of legal counsel, such failure “cannot be used to prove that the defendant willfully infringed the patent” at issue.²⁵⁵

²⁴⁵ *Id.*

²⁴⁶ *Id.*

²⁴⁷ *Id.* The joinder of parties limits implemented by the AIA “is a real benefit to parties who wish to avoid plaintiff-friendly districts, such as the Eastern District of Texas, and who want a better chance to be able to transfer a lawsuit to a more desirable location.” *Id.*

²⁴⁸ *Id.*

²⁴⁹ *Id.*

²⁵⁰ *Id.*

²⁵¹ *Id.*

²⁵² *Id.*

²⁵³ *Id.*

²⁵⁴ *Id.*

²⁵⁵ *Id.*

5. False Marketing Cases

Prior to the AIA, any person could sue for false marketing under the false marketing statute qui tam provision.²⁵⁶ The AIA eliminates false marketing lawsuits for “any person,” except for cases filed by a competitor who can prove competitive injury or the U.S. government.²⁵⁷ This provision of the AIA applies retroactively from the date of enactment.²⁵⁸

D. The AIA’s Answers for Gene Patents and Scientific Research

While the AIA implemented numerous new initiatives and protocols to revamp the U.S. patent system, gene patents were not included in the overall master plan. On the same day that the AIA was officially signed into law by President Obama, plans were announced for the development of a national bioeconomy blueprint by January 2012.²⁵⁹ The Obama Administration announced a plan to create a bioeconomy blueprint that will detail “[a]dministration-wide steps to harness biological research innovations to address national challenges in health, food, energy, and the environment.”²⁶⁰

Biological research, specifically genetic research, plays a significant role in the United States’ economy and the well being of Americans.²⁶¹ To ensure that this trend continues, the bioeconomic blueprint is intended to “focus on reforms to speed up commercialization and open new markets, strategic [research and development] investments to accelerate innovation, regulatory reforms to reduce unnecessary burden on innovators, enhanced workforce training to develop the next generation of scientists and engineers, and the development of public-private partnerships.”²⁶²

In addition to the bioeconomic blueprint, the National Institute of Health (“NIH”) will be launching a program aimed to assist biotechnical entrepreneurs.²⁶³ The NIH plans to establish a National Center for Advancing Translational Sciences (“NCATS”) that will identify barriers in the way of scientific progress, such as financial barriers.²⁶⁴ Though it appears that the Obama Administration, through the AIA, is taking initiative to promote genetic research and to foster scientific progress, in reality, separate regulations in conjunction with the AIA are required to establish specific guidelines for gene patents to promote scientific research and collaboration, which will ultimately result in faster diagnostic and health discoveries.

Overall, the AIA implements positive changes to the U.S. patent system; however, the AIA failed to establish guidelines specifically designed to regulate gene patents. Gene patents have been a topic of controversy since the Supreme

²⁵⁶ *Id.*

²⁵⁷ *Id.*

²⁵⁸ *Id.*

²⁵⁹ *President Obama Signs America Invents Act, supra* note 19.

²⁶⁰ *President Obama Signs America Invents Act, supra* note 19.

²⁶¹ *See President Obama Signs America Invents Act, supra* note 19.

²⁶² *President Obama Signs America Invents Act, supra* note 19.

²⁶³ *President Obama Signs America Invents Act, supra* note 19.

²⁶⁴ *President Obama Signs America Invents Act, supra* note 19.

Court's decision in *Chakrabarty*.²⁶⁵ Numerous concerns have been raised through case law and scholarly articles outlining the issues that need to be addressed by legislation.²⁶⁶ Instead of correcting the problem, the AIA has remained silent. The answer is not to conduct more studies and launch separate programs in conjunction with the AIA to develop "blueprints" for genetic and scientific research as suggested by the Obama Administration. The time for action is now. Genetic research can and will lead to the discovery of new diagnostic treatments and cures; cures that could have saved Kathy Hopkins and Greg Knittel. The answers that genetic research can provide society are eminent, and the discoveries genetic research can provide to healthcare services is potentially world changing. Gene patents should be categorized in a separate patent category within the AIA, under regulations specifically designed to promote scientific research and collaboration that will in turn foster faster results for diagnostic technologies and treatments.

V. THE IMPACTS OF GENE PATENTS ON SCIENTIFIC RESEARCH AND THE NEED FOR LEGISLATIVE GUIDELINES

The U.S. patent system needs to be adapted for the rapidly changing field of genetics by implementing new regulations for gene patents specifically designed to promote scientific research and collaboration.²⁶⁷ To adapt for the rapidly changing field of genetics, the AIA, and thus the U.S. patent system, should be amended to implement the following regulations specifically geared for gene patents:

- (1) establish a new patent category specifically engineered for gene patents;
- (2) reduce the period of gene patent protection to promote collaboration among researchers and foster faster research results;
- (3) require individuals with patents to share their research on the GenBank database to further promote collaboration and render faster results; and lastly,
- (4) implement patent pooling as another mechanism to promote collaboration and increase discovery rates.

Each proposal will be discussed in detail below.

A. *The Creation of a New Patent Category: Gene Patents*

Instead of categorizing and regulating gene patents under the same guidelines as utility patents, separate legislation should be implemented to categorize and regulate gene patents as separate entities. Currently, the patent system only identifies three categories of patents: (1) utility patents, (2) design patents, and (3) plant patents.²⁶⁸

²⁶⁵ See *supra* Part II.A.3 (discussing society's split views on gene patents).

²⁶⁶ See *supra* Part II.A.3.

²⁶⁷ THE NATIONAL RESEARCH CENTER, REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH: INTELLECTUAL PROPERTY RIGHTS, INNOVATION, AND PUBLIC HEALTH 4 (Stephen A. Merrill & Anne-Marie Mazza, eds., 2006) available at <http://www.nap.edu> (enter "11487" into search box).

²⁶⁸ *Patents*, *supra* note 69. *All About Patents*, UNITED STATES PATENT AND TRADEMARK OFFICE, <http://www.uspto.gov/smallbusiness/patents/types.html> (last visited Feb. 18, 2013).

Gene patents are a subcategory under utility patents.²⁶⁹ Plant patents are given to inventors that have “invented or discovered and asexually reproduced a distinct and new variety of plant, other than a tuber propagated plant or a plant found in an uncultivated state.”²⁷⁰ To invent or discover a “distinct and new variety of plant” that is not found in nature, researchers must use plant DNA, similar to the process researchers use to extract gene sequences from human DNA.²⁷¹

Arguably, if plant patents are categorized as a separate patent type, gene patents should be categorized as a separate patent type as well.²⁷² If the USPTO allows researchers to patent extracted plant DNA gene sequences that are not found in nature as regulated by plant patents, then gene patents should be categorized in a similar fashion since the underlying techniques and scientific mechanisms are so similar. Therefore, the AIA should, using the plant patent category as a model, establish a fourth patent category specifically engineered to regulate and promote gene patents.

B. A Reduction in Patent Protection to Implement Collaboration

In addition to creating a fourth patent category for gene patents, additional guidelines should be established to implement a shorter protection period to promote scientific collaboration, and in turn, stimulate faster discoveries. To achieve the maximum benefits from research, a collaboration system must be implemented to emphasize the need for data sharing.²⁷³

As stated by the National Research Council (NRC) in 2003:

Community standards for sharing publication-related data and materials should flow from the general principle that the publication of scientific information is intended to move science forward. More specifically, the act of publishing is a large quid pro quo in which authors receive credit and acknowledgement in exchange for disclosure of their scientific findings. An author’s obligation is not only to release data and materials to enable others to verify or replicate published findings but also to provide them in a form on which other scientists can build with further research. All members of the scientific community – whether working in academia, government, or a commercial enterprise – have equal responsibility for upholding community standards as participants in the

²⁶⁹ Utility Examination Guidelines, 66 Fed. Reg. 1093 (Jan. 5, 2001).

²⁷⁰ *General Information About 35 U.S.C. 161 Plant Patents*, UNITED STATES PATENT AND TRADEMARK OFFICE, <http://www.uspto.gov/web/offices/pac/plant/> (last visited Nov. 21, 2011).

²⁷¹ *Id.*

²⁷² The Plant Patent Act of 1930 was the first intellectual property law to cover biological materials. Cary Fowler, Ph.D., *The Plant Patent Act of 1930: A Sociological History of Creation*, 82 J. PAT. & TRADEMARK OFF. SOC’Y 621, 621 (2000). The Plant Patent Act brought protection for “asexually reproduced varieties of domesticated plants (for example, apple, pear, rose, etc.)” *Id.* Since the passage of the Act its protection has extended to include “sexually reproduced plant varieties, micro-organisms, genes and gene complexes, characteristic and products.” *Id.*

²⁷³ THE NATIONAL RESEARCH CENTER, *supra* note 267, at 83.

publication system, and all should be equally able to derive benefits from it.²⁷⁴

Collaboration is a key element to the success of scientific research. Patents by definition “exclude others from making, using, offering for sale, or selling [an] invention [in] the United States.”²⁷⁵ Both utility patents and plant patents provide twenty years of protection.²⁷⁶ Only when the patent expires does the patented subject matter become public domain.²⁷⁷ Legally excluding others from making or using a patented sequence for twenty years significantly prohibits the progression of science and the discovery of diagnostic techniques and treatments for diseases, such as cancer and ALS.

It is unnecessary to exclude the scientific community from working with patented gene sequences for twenty years. Two of the main reasons scientists seek patents are for recognition of their work and to preserve the opportunity to continue working with their discovery or invention without the pressure of competition. Neither of these functions requires twenty years of protection. Instead of granting a long term

²⁷⁴ THE NATIONAL RESEARCH CENTER, *supra* note 267, at 83 (citation omitted). The National Research Council (NRC) was organized in 1916 by the National Academy of Sciences. THE NATIONAL RESEARCH CENTER, *supra* note 267, at iii. The NRC was put together “to associate the broad community of science and technology with the Academy’s purposes of furthering knowledge and advising the federal government.” THE NATIONAL RESEARCH CENTER, *supra* note 267, at iii. “The Council has become the principal operating agency of both the National Academy of Sciences and the National Academy of Engineering in providing services to the government, the public, and the scientific and engineering communities.” THE NATIONAL RESEARCH CENTER, *supra* note 267, at iii. The Council is administered by the National Academy of Sciences and the National Academy of Engineering, along with the Institute of Medicine. THE NATIONAL RESEARCH CENTER, *supra* note 267, at iii. The National Academy of Sciences is a nonprofit, private organization. THE NATIONAL RESEARCH CENTER, *supra* note 267, at iii. It is comprised of “distinguished scholars engaged in scientific and engineering research, dedicated to the furtherance of science and technology and to their use for general welfare.” THE NATIONAL RESEARCH CENTER, *supra* note 267, at iii. The National Academy of Sciences has a “mandate that requires it to advise the federal government on scientific and technical matters” that was chartered by Congress in 1863. THE NATIONAL RESEARCH CENTER, *supra* note 267, at iii. The National Academy of Engineering was established under the charter of the National Academy of Sciences in 1964. THE NATIONAL RESEARCH CENTER, *supra* note 267, at iii. It shares responsibilities with the National Academy of Sciences in advising the federal government. THE NATIONAL RESEARCH CENTER, *supra* note 267, at iii. The Academy of Engineering “sponsors engineering programs aimed at meeting national needs, encourages education and research, and recognizes the superior achievements of engineers.” THE NATIONAL RESEARCH CENTER, *supra* note 267, at iii. The Institute of Medicine was founded by the National Academy of Sciences in 1970 with the purpose of securing services of members from the appropriate professions in examining policy matters pertaining to the health and welfare of the public. THE NATIONAL RESEARCH CENTER, *supra* note 267, at iii. “The Institute acts under the responsibility given to the National Academy of Sciences by its congressional charter to be an adviser to the federal government and, upon its own initiative, to identify issues of medical care, research, and education.” THE NATIONAL RESEARCH CENTER, *supra* note 267, at iii.

²⁷⁵ *Patents*, *supra* note 268.

²⁷⁶ *Patents*, *supra* note 268.

²⁷⁷ *General Information*, *supra* note 270.

of protection, the period of protection should be shortened to ten years with the opportunity for researchers to renew for an additional five years pursuant to substantial evidence of significant research development, otherwise the term ends, and the patented subject matter becomes public domain.

The HGP was planned to last fifteen years but only took thirteen years.²⁷⁸ The key to the success of the HGP was collaboration. If the HGP, through a collaborative effort, discovered 20,500 genes of the human genome, then it is reasonable to assume that any researcher, through collaborative efforts, can make substantial progress in research to renew patent protection for an additional five years.²⁷⁹ If a researcher cannot provide evidence to show substantial progress then the patented gene sequence should become public domain to give others the opportunity to study the previously patented subject matter.

C. GenBank Database

In addition to creating a new category for gene patents and reducing the duration of patent protection to further promote collaboration and scientific progress, Congress should implement the GenBank database as a mandatory system within the U.S. gene patent system.²⁸⁰ The GenBank is a free, public database sponsored by the NIH that houses genome sequences generated by the HGP, the HapMap Project, and other scientific research.²⁸¹ The NIH designed the GenBank “to provide and encourage access within the scientific community to the most up to date and comprehensive DNA sequence information.”²⁸² By forcing all scientists that obtain a gene patent through USPTO to upload their research and findings as they progress through the protected patent period to GenBank, a complete international database will exist that will influence not only patented projects, but this data base will also spark new findings and inventions for new patents.

GenBank is the key to implementing collaboration into a system that has historically and legally prevented it.²⁸³ Currently, the NIH has “no restrictions on the

²⁷⁸ *About Human Genome Project*, *supra* note 44.

²⁷⁹ *See About Human Genome Project*, *supra* note 44; *The Human Genome Project: A New Reality*, *supra* note

²⁸⁰ *Genetics and Patenting*, *supra* note 73. THE NATIONAL RESEARCH CENTER, *supra* note 267, at 135-37.

²⁸¹ *GenBank Overview*, NCBI, <http://www.ncbi.nlm.nih.gov/genbank/> (last visited Nov. 21, 2011). According to the release notes of the current version as of the time of writing, there are approximately 162,886,727 loci and 150,141,354,858 bases in 162,886,727 sequence records contained in GenBank. *Id.*; *Genetic Sequence Data Bank*, NCBI, (Feb. 15, 2013), <ftp://ftp.ncbi.nih.gov/genbank/gbrel.txt>. “GenBank is part of the International Nucleotide Sequence Database Collaboration, which comprises the DNA Databank of Japan (DDBJ), the European Molecular Biology Laboratory (EMBL), and the GenBank at NCBI. These three organizations exchange data on a daily basis.” *Id.*

²⁸² *Id.*

²⁸³ The key to further scientific research is collaboration among scientists and the sharing of data and research:

Requests for material transfers between and within the industrial and academic sectors are widespread, although not of high frequency. About 60 percent of industry respondents and 75 percent of academic respondents initiated at least one request in

use or distribution of the GenBank data” and has no means of assessing claims of patented intellectual property.²⁸⁴ The NIH “cannot provide comment or unrestricted permission concerning the use, copying, or distribution of the information contained in GenBank.”²⁸⁵ This problem can easily be fixed by requiring users to register before being able to use the database, tracking the specific sequences and the frequency of each user, tracking the contributions users upload, and requiring users with patents to provide proof upon submittal, and in turn clearly marking patented submissions as patent protected work.²⁸⁶ Protecting patented work and allowing researchers to share research in a free, open, and protected environment will allow for significant progress in diagnostic and treatment technologies that will save millions of lives.

D. Patent Pooling

Potential ramifications of the GenBank database in terms of collaboration include the desire of other researchers to partake in a patented project. To allow for such occurrences, the USPTO should implement gene patent pooling within the regulations of gene patents.²⁸⁷ “A patent pool is an agreement between two or more patent owners to license one or more of their patents to one another or third parties.”²⁸⁸ Patent pooling can alternatively be defined as “the aggregation of intellectual property rights which are the subject of cross-licensing, whether they are

the last two years. Approximately 40 percent of industry respondents and 69 percent of academic scientists had received such a request in the same period. Rates of initiation and receipt of requests are about the same for those doing drug discovery and those doing basic research.

THE NATIONAL RESEARCH CENTER, *supra* note 267, at 128.

²⁸⁴ THE NATIONAL RESEARCH CENTER, *supra* note 267, at 128.

²⁸⁵ *GenBank Overview*, *supra* note 281.

²⁸⁶ Another solution to current lack of protection offered by GenBank is to implement an “experimental use exemption” policy. THE NATIONAL RESEARCH CENTER, *supra* note 267, at 144. The Committee on Intellectual Property Rights in Genomic and Protein Research and Innovation suggest that:

Congress should consider exemption research “on” inventions from patent infringement liability. The exemption should state that making or suing a patented invention should not be considered infringement if done to discern or to discover: (a) the validity of the patent and scope of afforded protection, (b) the features, properties, or inherent characteristics or advantages of the invention; (c) novel methods of making or using the patented invention; or (d) novel alternatives, improvements, or substitutes.

THE NATIONAL RESEARCH CENTER, *supra* note 267, at 145.

²⁸⁷ THE NATIONAL RESEARCH CENTER, *supra* note 267, at 145.

²⁸⁸ THE NATIONAL RESEARCH CENTER, *supra* note 267, at 145 (*quoting* Joel I. Klein, An Address to the American Intellectual Property Law Association, on the Subject of Cross-Licensing and Antitrust Law (May 2, 1997) (citation omitted)); JEANNE CLARK ET AL., UNITED STATES PATENT AND TRADEMARK OFFICE, PATENT POOLS: A SOLUTION TO THE PROBLEM OF ACCESS IN BIOTECHNOLOGY PATENTS? 4 (2000), *available at* www.uspto.gov/web/offices/pac/dapp/opla/patentpool.pdf.

transferred directly by patentee to licensee or through some medium, such as a joint venture, set up specifically to administer the patent pool.”²⁸⁹

Patent pools have played an important role within the U.S. patent system for over 150 years.²⁹⁰ There is no conceivable reason why this form of patent cannot be implemented within gene patent regulations. Patent pools offer greater innovation because more individuals can work with patented subject matter.²⁹¹ This permits parallel research because both the patented researcher and the licensed researchers can study a patented subject matter, which results in faster discoveries and results.²⁹² Patent pooling within the realm of gene patents will only further promote scientific research and collaboration.

The AIA needs to be amended to include legislation, as described above, to better regulate gene patents.²⁹³ The goals of gene patents should not be focused on name recognition or monetary purposes but instead on discovering diagnostic tools and treatments that will save millions of lives. By implementing guidelines that promote collaboration and scientific research, vast innovations and breakthroughs will occur and will bring about diagnostic tools and treatments.

VI. CONCLUSION

The AIA is the foremost change in the U.S. patent system since 1952.²⁹⁴ While the AIA implements many new regulations within the U.S. patent system, no regulations were established to better regulate gene patents.²⁹⁵ The Obama Administration announced several plans and studies to look into the proper regulations for gene and biotechnology; however, this research is not needed as gene patents have been a topic of debate within intellectual property, science, and health care for the past three decades.²⁹⁶ Instead of wasting more time *researching* the best

²⁸⁹ See sources cited *supra* note 288.

²⁹⁰ JEANNE CLARK ET AL., *supra* note 288, at 4. Some aspects of patent pooling may create some disincentives particularly within the biopharmaceutical industry. THE NATIONAL RESEARCH CENTER, *supra* note 267, at 115. Commonly, patent pools are used in industries as a defense, but in the biopharmaceutical industry patents tend to be used on the offensive. THE NATIONAL RESEARCH CENTER, *supra* note 267, at 115. “Patent holders who enter a pool risk losing the more significant revenue they might receive if they exclusively licensed their patents.” THE NATIONAL RESEARCH CENTER, *supra* note 267, at 115. Whereas biotechnology companies tend to “prioritize the accumulation of patents” making them “attractive to buy-out.” Pharmaceutical companies tend to buy intellectual property as they need it. THE NATIONAL RESEARCH CENTER, *supra* note 267, at 115. “However, large companies no longer have the capital to continue buying whatever intellectual property they need, which may create an incentive for more patent pooling. There also may be an incentive for pooling when the complexity of intellectual property requires a pool for research to progress.” THE NATIONAL RESEARCH CENTER, *supra* note 267, at 115.

²⁹¹ REAPING THE BENEFITS, *supra* note 267, at 14-5.

²⁹² JEANNE CLARK ET AL., *supra* note 288, at 11.

²⁹³ See *supra* Part IV.

²⁹⁴ Bensen, *supra* note 163.

²⁹⁵ The Leahy-Smith America Invents Act, H.R. 1249, 120th Cong. (2011) (enacted), reprinted in www.uspto.gov/aia_implementation/bills-112hr1249enr.pdf.

²⁹⁶ See *supra* Part II.B.3 (discussing society’s split on gene patents).

practices to regulate gene patents, stricter guidelines need to be implemented within the AIA to regulate gene patents, and this implementation needs to occur quickly to keep up with the rapidly growing field of genetics.²⁹⁷

In order for the U.S. patent system to keep up with the rapidly growing field of genetics, the following suggestions should be implemented into the AIA to enforce stricter guidelines for gene patents: (1) a new category within the patent system should be created specifically for gene patents, as modeled from plant patents;²⁹⁸ (2) the period of gene patent protection should be reduced from twenty years to ten years, with the potential to renew for an additional five years through a showing of substantial scientific progress, to promote collaboration and faster results as seen through the HGP;²⁹⁹ (3) individuals that acquire gene patents must be required to share their research on the GenBank database to further promote collaboration and faster results, not only within the United States, but also internationally;³⁰⁰ and, (4) the AIA needs to implement patent pooling for gene patents as a means to support collaboration and the use of the GenBank, as well as promote faster results.³⁰¹ By implementing such regulations into the AIA, more scientific breakthroughs will occur, which will result in the discovery of new diagnostic technologies and treatments, and in turn will save millions of lives from common diseases that were once deemed incurable.

²⁹⁷ See *supra* Part I (discussing advances made in the genetics field).

²⁹⁸ See *supra* Part IV.A (discussing creation of a new patent category).

²⁹⁹ See *supra* Part IV.B (discussing rationale for this reduction).

³⁰⁰ See *supra* Part IV.C.

³⁰¹ See JEANNE CLARK ET AL., *supra* note 288, at 11.

